PB87-165080

Lindane: Position Document No. 2/3

(U.S.) Environmental Protection Agency
Washington, DC

Jun 80

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No. PB87 165080/AS

4. Title and Subtitle

POSITION DOCUMENT: LINDANE 2/3

5. Report Date JUNE 1980

6.

7. Author(s) EPA, OPP, REGISTRATION DIVISION

8. Performing Organization Rept. No. 540/9-87-153

9. Performing Organization Name and Address

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address

SAME AS #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

BEST AVAILABLE COPY

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

Dis.

c. COSATI Field/Group

18. Availability Statement:

PUBLICELY AVAILABLE

19. Security Class (This Report) UNCLASSIFIED

20. Security Class (This Page) UNCLASSIFIED

21. No. of Pages 194

22. Price

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

June 1980

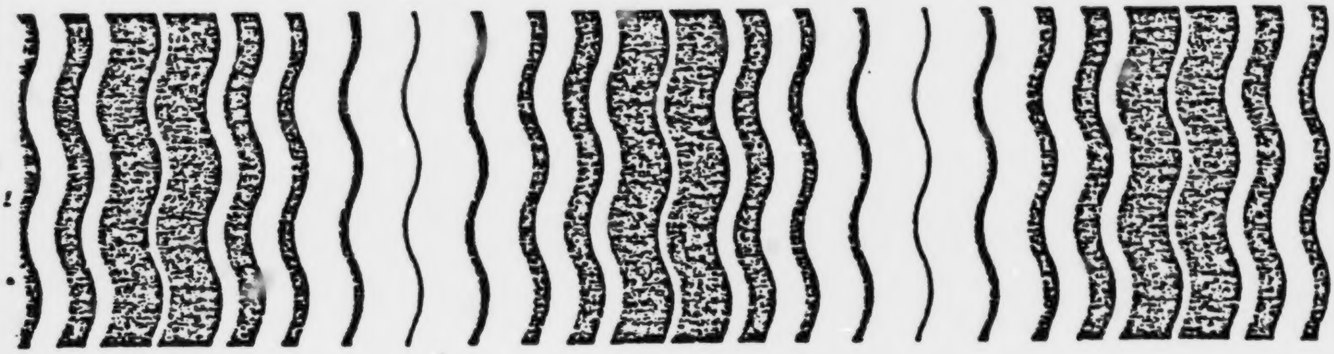
PB87-165080

Pesticides

EPA

Lindane

Position Document No. 2/3



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LINDANE: POSITION DOCUMENT 2/3

I. BACKGROUND

A. Introduction

1. Chemical and Physical Characteristics

Lindane is the gamma isomer of the insecticide 1,2,3,4,5,6-benzene hexachloride (BHC). Technical lindane contains at least 99 percent gamma-BHC, the remaining 1 percent consisting of other BHC isomers (Meister, 1978). Its melting point is 112.8°C. Its density is 1.85. Its vapor pressure is 3×10^{-5} mm Hg at 20°C. Lindane is soluble in various solvents, and its solubility in water varies with temperature (10 ppm at 20°C). Lindane is stable to light, heat, air, carbon dioxide, and strong acids, but is unstable in the presence of alkali (Blaquiere et al., 1972).

2. Registered Uses and Production

Environmental Protection Agency (EPA or "the Agency") records show registrations for about 700 lindane products (270 registrants) and about 85 federally recognized intrastate registrations of state-registered products. During the BHC RPAR ("rebuttable presumption against registration and reregistration") proceedings, registrants of BHC and BHC/lindane products were allowed to change their registrations to lindane to avoid cancellation. All BHC registrations were either voluntarily cancelled or amended to become lindane registrations.

Current registrations of lindane products reflect a wide range of uses. The major use categories are hardwood logs and lumber, seed treatment of small grains and corn, and livestock, but lindane is also used on Florida avocados, ornamental plants, cucurbits, Christmas trees, pecan orchards, commercial forests, existing structures (mainly homes), Hawaiian pineapples, pets and their premises, household pests, etc. Lindane products are formulated as wettable powders, emulsifiable concentrates, oil-base sprays, dusts, granules, and pressurized products, including "one shot" vaporizers, aerosols, and smoke products (Meister, 1978).

Hooker Chemicals and Plastics Corporation of Niagara Falls, New York, has been the sole domestic manufacturer of lindane. In May 1976, however, Hooker halted production of lindane pending completion of EPA's review of the chemical, and is currently importing lindane to supply its customers (EPA 1978f). For the years 1972 through 1976, Hooker manufactured a total of 3,684,000 pounds of lindane and a total of 4,914,900 pounds of the related compound fortified BHC (FBHC), which contains 42-43 percent gamma isomer, for a combined total of 8,598,900 pounds of gamma-BHC isomer. Hooker's records show a pattern of declining production during those five years. In 1972, 808,000 pounds of lindane and 1,621,960 pounds of FBHC were manufactured, for a combined total of 2,429,960 pounds. In 1976, the comparable figures were 702,000 pounds of lindane and 196,080 pounds of BHC, for a combined total of 898,080 pounds.[1]

3. Tolerances

Tolerances for residues of lindane in or on raw agricultural commodities are listed in 40 CFR 180.133 as follows: 7 parts per million (ppm) in or on the fat of meat from cattle, goats, horses, and sheep; 4 ppm in or on the fat of meat from hogs; 3 ppm in or on cucumbers, lettuce, melons, mushrooms, pumpkins, squash, summer squash, and tomatoes; 1 ppm in or on apples, apricots, asparagus, avocados, broccoli, brussels sprouts, cabbage, cauliflower, celery, cherries, collards, eggplants, grapes, guavas, kale, kohlrabi, mangoes, mustard greens, nectarines, okra, onions (dry bulb only), peaches, pears, peppers, pineapples, plums (fresh prunes), quinces, spinach, strawberries, and Swiss chard; and 0.01 ppm (negligible residue) in or on pecans.

B. Applicable Sections of FIFRA

Section 12(a)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) prohibits the sale or distribution of pesticide products which are not registered by the EPA Administrator, and Section 3 of the Act sets forth the registration procedures. Before a pesticide may be registered, however, the Administrator must determine that its use will not result in "unreasonable adverse effects on the environment," defined in Section 2(bb) of FIFRA as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

In other words, any decision on pesticide registration must take into account both the risks and the benefits associated with the pesticide's use.

Under Section 6(b) of FIFRA the Administrator may issue a notice of intent to cancel the registration of a pesticide or to change its classification if it appears that the pesticide or its labeling "does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Thus, the Administrator may cancel the registration of a pesticide that no longer satisfies the statutory standard for registration; this standard requires, among other things, that the pesticide "perform its intended function without unreasonable adverse effects on the environment" [FIFRA 3(c)(5)(C)]. The Administrator may also change the classification of any use of a pesticide if he determines that such a change "is necessary to prevent unreasonable adverse effects on the environment" [FIFRA 3(d)(2)].

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[1] During those same years, Hooker exported declining amounts of lindane (232,120 pounds in 1972; 32,300 pounds in 1976) and FBHC (1,456,320 pounds in 1972; 47,480 pounds in 1976). According to USDA, declining amounts of lindane were imported to the U.S. during the years 1972-1974 (132,939 pounds in 1972, 5,757 pounds in 1973, and 3,525 pounds in 1974). No lindane was imported in 1975 or 1976. No FBHC was imported 1972-1976.

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C. The "RPAR" Process

To implement its authorized functions, the Agency has designed the Rebuttable Presumption Against Registration (RPAR) process, which involves gathering data on the risks and benefits associated with the uses of suspect pesticides. By allowing all interested parties to participate by submitting information, the process enables EPA to make balanced decisions concerning problem pesticides.

The RPAR process is set forth in 40 CFR 162.11, which describes various risk criteria and provides that an RPAR shall arise if the Agency determines that any of these criteria has been met.

Once a rebuttable presumption has arisen, registrants, applicants, and interested persons may submit evidence in rebuttal, or in support, of the presumption. These parties may also submit evidence on the economic, social, and environmental benefits of any use of the pesticide. If the presumptions of risk are not rebutted, the evidence pertaining to benefits must be evaluated and considered together with the evidence pertaining to risk. Various risk-reduction measures and their costs are analyzed. The Agency then determines whether the pesticide may be regulated so that a balance is achieved between risks and benefits. If the statutory balance cannot be reached for any given use, the registrations for that use must be cancelled.

D. Regulatory History

Pesticides containing lindane have been federally registered since the early 1950's. A summary of regulatory actions on lindane through 1975 is given in Lindane: Position Document 1 (EPA 1977a).

On February 17, 1977, the Agency published a notice of rebuttable presumption against registration (RPAR) and continued registration of pesticide products containing lindane in the Federal Register (EPA 1977b). Position Document 1 contains background and supporting data for the presumptions of risk cited in the RPAR notice.

On April 28, 1977, Continental Chemiste Corporation petitioned the U.S. Court of Appeals for the Seventh Circuit to issue a writ of mandamus requiring EPA to withdraw the RPAR notice against that company's lindane smoke insecticide products. The company argued that the notice violated the mandate of a previous decision by the Court to set aside the

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Agency order cancelling Continental Chemiste lindane products [461 F.2d 331 (7th Cir. Docket No. 71-1828, 1972)]. This petition was denied on June 7, 1977.

Certain pesticide products which have been subject to EPA regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, also fall within the statutory definition of "new drug" in the Federal Food, Drug, and Cosmetic Act (FFDCA) and have been subject concurrently to regulation by the Food and Drug Administration (FDA). EPA and FDA published procedures for joint review and approval of products that fall within the statutory definitions of both "pesticide" and "drug" in the Federal Register of December 22, 1971 (36 FR 242334), and September 6, 1973 (38 FR 24233). On November 9, 1979, however, an EPA regulation was published [Federal Register 44(215):63749] which exempts from FIFRA registration requirements all pesticides which are designated solely for use on human persons and as such are considered new drugs as defined by Section 201(p) of the FFDCA. All lindane products designated solely for use on human persons will therefore be subject henceforth to regulation by the FDA.

E. Bases for the Rebuttable Presumption

The lindane RPAR notice cited three risk criteria which lindane had met or exceeded: (1) acute toxicity to aquatic organisms [40 CFR 162.11(a)(3)(i)(B)(3)], (2) oncogenic effects in test animals [40 CFR 162.11(a)(3)(ii)(A)], and (3) chronic and/or delayed toxicity causing reproductive or fetotoxic effects in test animals [40 CFR 162.11(a)(3)(ii)(B)].

In addition to these criteria, the RPAR notice listed four other possible adverse effects of lindane for which insufficient evidence existed to initiate a rebuttable presumption. The Agency requested registrants and other interested parties to submit data on the following effects: (1) mutagenicity, (2) blood dyscrasias, (3) acute hazards to humans and domestic animals, and (4) population reduction in nontarget avian species. Information was solicited also on the additional issue of the possible isomerization of lindane (gamma-BHC) to the alpha and beta isomers of BHC, which have been shown to be oncogenic in rodents.

F. Legislative Background

FIFRA and its regulations require EPA to review both the risks and the benefits of the uses of pesticides. Since issuing the RPAR notice for lindane (EPA 1977b), the Agency has received rebuttal comments and has conducted in-depth risk and benefit analyses. This position document (PD 2/3) responds to the rebuttal comments, summarizes the risks and benefits associated with lindane, and recommends a regulatory option for each use.

This PD 2/3 also satisfies the substantive requirements of an environmental impact statement. It fully discusses the scope of the problem to be regulated, the process for selecting the alternative courses of action, and the reasons for the Agency's proposed final decision. It contains five parts. Part I is this introductory section. Part II presents an evaluation of potential risks of lindane. It includes descriptions of the relevant laboratory data on risks, exposure data, and the Agency's present risk assessment. Part III is a summary analysis of the economic benefits of lindane. Part IV presents the process by which, on a use-by-use basis, the Agency developed a range of the regulatory options and selected specific options for in-depth evaluation. Finally, Part V proceeds with a risk/benefit analysis of the regulatory options, use by use, and summarizes the regulatory actions which the Agency proposes to take concerning the registration and continued registration of pesticide products containing lindane.

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II. ANALYSIS OF REBUTTALS AND ASSESSMENT OF RISK

As stipulated in 40 CFR 162.11(a)(4) respondents can rebut any presumption against a pesticide by showing 1) that the Agency's initial determination of risk was in error or 2) that given current use patterns, exposure to the pesticide is not likely to result in any significant chronic or acute adverse effects. The rebuttable presumption against registration and continued registration of pesticide products containing lindane drew responses concerning the three presumptions of oncogenicity, reproductive and fetotoxic effects, and acute toxicity to wildlife, aquatic organisms. Comments were also received concerning the possible adverse effects of mutagenicity, blood dyscrasias, acute hazards to humans and domestic animals, and population reduction in nontarget avian species, as well as the additional issue of isomerization. Submissions pertaining to the rebuttable presumptions and to other possible adverse effects, together with the Agency's responses and additional findings, are reviewed in Subsection II.A below. Rebuttal comments pertaining to exposure are addressed in Subsection II.B, "Exposure Analysis." The Agency's determinations on risk are given in Subsection II.C, "Risk Assessment."

A. Rebuttal Analysis

1. Attempts to Rebut the Presumption of Oncogenicity

In Position Document 1, the Agency announced a presumption of oncogenic effects on the basis of three laboratory studies which observed oncogenic responses when lindane was tested on mice. (See Table II-1.) Goto et al. (1972) fed 5-week-old male mice 300 or 600 parts per million (ppm) lindane for 26 weeks. Liver tumors were seen in 50 percent of the 10 animals which ingested 600 ppm lindane, and a 2-fold increase in the ratio of liver weight to body weight was observed at the same dose. Five treated animals (25 percent) died early in the study. No oncogenic or other liver effects were observed in the animals ingesting 300 ppm lindane.

Hanada et al. (1973) treated 6-week-old male and female mice with 100, 300, or 600 ppm lindane for 32 weeks. The animals were thereafter maintained on a basal diet for 6 weeks and sacrificed 38 weeks after feeding started. Tumors were found in 1 of 3 females and in 3 of 4 males ingesting 600 ppm lindane for a combined rate of 64 percent (7 of 11). No tumors were observed in the 29 control animals, in the 18 animals ingesting 100 ppm, or in the 16 animals ingesting 300 ppm lindane. Doses of 300 ppm, however, produced atypical proliferation of liver cells.

Thorpe and Walker (1973) fed 4-week-old male and female mice 400 ppm lindane for 52 to 110 weeks. A statistically significant increase in the incidence of hepatic liver tumors was reported, as well as metastases to the lung in the lindane-fed animals relative to controls. Ninety-six percent of the males had tumors, including 11 percent metastases. Ninety-five percent of the females had liver tumors with no metastases.

Table II-1. Comparison of Oncogenicity Studies Cited in the Lindane RPAR Notice and the NCI Study in Mice

	Thorpe and Walker (1973)	Goto et al. (1972)	Hanada et al. (1973)	NCI Study (1977)*
Strain	CF_1	ICR-JCL	dd	$B_6C_3F_1$
Age	4 weeks	5 weeks	6 weeks	5 weeks
Sex	Both	Male	Both	Both
Number/Group	29-45	20	10-14	50
Dose (ppm) in diet	400	300 600	100 300 600	80 160
Duration	2 years	26 weeks	37-38 weeks	80 weeks and 30 weeks of observation
Results	Liver tumors in males and females, 96% males and 95% of females treated compared to 23-24% of controls (p <.0001).	Liver tumors in males (50% of treated males at 600 ppm). (P=.004 no tumors in unreported controls.)	Liver tumors in males and females (3 of 4 surviving males, 1 of 3 females at 600 ppm; no tumors reported in controls). Significant in males (p <.013 at 600 ppm.)	Hepatocellular carcinoma in male mice at low dose-level of 80 ppm (P=0.001.) High-dose group showed less significant results (9/46 vs. 5/49; p=0.10).

*The final results of the National Cancer Institute (NCI) carcinogenicity bioassay are included here for purposes of comparison. (Only the preliminary results were available at the time PD1 was issued.) For discussion, see Subsection II.A.1.d of text.

Liver tumors were found in 24 percent of the control animals, but no metastases were observed. Toxic effects leading to death occurred during the first 3 months of lindane feeding for approximately 15 percent of the animals. Moreover, for the entire 110-week experimental period, there was a 90-percent total fatality record for lindane-fed animals as compared to 68 percent for controls.[1]

In response to our request for rebuttals and additional information concerning oncogenicity as a presumed risk of lindane, the Agency received nine responses from three registrants: Paper Products, Inc. (30000/10:#41), Hooker Chemicals (30000/10:#42), and Reed and Carnrick Pharmaceuticals (30000/10:#6C). The Agency has reviewed the material submitted and has concluded that it does not invalidate the three studies cited in the lindane RPAR notice and in PD1 as bases for the presumption of oncogenicity, nor is the presumption otherwise rebutted (EPA 1978a;EPA 1978b).[2]

a. Attempted Rebuttal Pertaining to Dosages Used in Testing

Paper Products, Inc. (30000/10:#41) challenged the Agency's presumption of oncogenicity by contesting the dosage levels used in the three studies on which the presumption was based.

Concerning the Goto and Hanada experiments, the registrant argued that the lindane dosages used were so high that only acute toxic effects could be assessed. Specifically, the grounds for contention were 1) that so many animals died from toxic effects that chronic oncogenic potential could not be assessed from the few remaining animals, and 2) that the acute oral LD_{50} dose for these species was exceeded. Concerning the Thorpe and Walker experiment, the registrant argued that the study constitutes weak evidence of human carcinogenicity for four reasons. (1) The dose used (400 ppm) was too high to allow meaningful conclusions about carcinogenicity.[3] (2) The strain used (CFI) is prone to hepatomas of unknown causes. (3) Thorpe and Walker themselves questioned the biological significance of the tumors, chiefly because many co-factors are known to influence the development of liver tumors. (4) The spontaneous incidence of extrahepatic tumors is very high (82 percent), and the lindane treatment does not increase tumor incidence, but merely shifts the tumor sites to the liver.

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[1] Also mentioned in PD1 were the following lindane studies which reported no oncogenic effects: Nagasaki et al. (1973) and Herbst et al. (1975), mouse studies; Fitzhugh et al. (1950), Truhaut (1954), Ito et al. (1975), and Ortega et al. (1957), rat studies.

[2] The related issue of whether lindane isomerizes in the environment to alpha-BHC or in rats to alpha-and beta-BHC, both of which have been shown to induce oncogenic effects in rodents, is addressed in Subsection II.A.4.e.

[3] In this connection, the registrant argued the following points:

1) 15 percent of the animals died in the first 3 months,
2) 400 ppm is 70 percent of the LD_{50} in the species, and
3) only 3 percent of the females and 17 percent of the males survived the entire experiment.

The Agency rejects the above arguments. With regard to the Goto and Hanada experiments, Paper Products, Inc. did not state the LD_{50} dose for either strain of mice used in testing. Nor did the registrant cite the source for the contention that the LD_{50} for the animals was exceeded. The argument based on LD_{50} values is thus incomplete, and the mortality and body weight gain in the studies themselves must be used to evaluate the toxicity. The Agency grants that the mortality in the Hanada study is high,[4] and this, together with the relatively short duration of the experiment and the small number of test animals, makes the study in itself only a weak indicator of carcinogenicity. However, the incidence of tumors in males was unmistakably high over a short period of time (3 out of 4 lindane-treated males had tumors as compared with 0 out of 14 controls; $p = 0.013$), and this suggests that lindane may be carcinogenic in dd strain mice. Because Goto did not state the percent survival throughout the experiment, it is not possible to evaluate whether non-tumor mortality appreciably influenced tumor incidence. Body-weight gain was normal, but considerable liver enlargement indicated that lindane was in some way toxic to the liver. The omission of control group pathology data in this study permits only a qualitative conclusion that lindane apparently induced early stages of hepatocellular carcinoma.

In both the Hanada and Goto experiments, the liver lesions consisted of tumors of the liver. In both experiments, the findings are consistent with either carcinomas or the early stages of hepatocellular carcinoma.

With regard to the Thorpe and Walker experiment, the Agency acknowledges that mortality among the treated group (especially females) was higher than among the controls. Nonetheless, the cumulative tumor incidence among treated animals at three different stages (17, 21, and 25 months) of the experiment was significantly higher than among controls. Early mortality from the toxic effects of lindane was thus not great enough to mask the carcinogenic effects. Regardless of other possible factors, the lindane-treated animals definitely developed a higher incidence of liver tumors than did controls. This is sufficient cause for concern that lindane could have a carcinogenic effect in humans. Concerning the registrant's contention that lindane treatment merely transferred tumors to the liver, the Agency points out 1) that it is extremely difficult to interpret changes in the incidence of tumors at several sites combined, as was done with extrahepatic tumors; and 2) that the decrease in the incidence of extrahepatic tumors was not statistically significant. For these reasons the reduction in extrahepatic tumors does not decrease the significance of the tumors induced by lindane.

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[4] Out of the initial group of approximately 10 animals, only 3 females and 4 males survived to 36 weeks at 600 ppm.

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b. Attempted Rebuttal Pertaining to Liver Toxicity as a Test Interference

Paper Products, Inc. (30000/10:#41) argued also that not only lindane but any compound given in doses large enough to produce extensive liver toxicity will produce liver tumors. The further implication was that, at doses low enough to be non-toxic to the liver, no carcinogenic response would occur, and the compound would be safe.

The Agency rejects this argument. The registrant's contention is based on a hypothesis which has not been established. It is unfortunate that liver toxicity is not ordinarily examined in carcinogenesis tests, and information on this point is seldom available. Until such a correlation is shown, the Agency's position is that the coincidence of liver toxicity with a carcinogenic response is not sufficient reason for disregarding the carcinogenic potency of a compound.

c. Additional Studies Submitted in Attempted Rebuttal

In attempt to counter the three studies on which the presumption of oncogenicity was based, Hooker Chemicals (30000/10:#42) cited an 80-week study by Weisse and Herbst (1976). Weisse and Herbst studied the carcinogenic potential of lindane at 12.5, 25, and 50 ppm dose levels in the food of NMRI male and female mice, 250 of each sex total. The reported results showed no evidence of increased tumorigenicity.

The Agency rejects this rebuttal attempt. Weisse and Herbst used a different strain of mice and lower dose levels than did the three oncogenicity studies cited in the RPAR notice. Uncertainties about the maximum tolerated dose in this strain make it difficult to assess whether the dose was high enough to cause a statistically observable response. The three independent studies cited as bases for the original presumption of oncogenicity showed a definite excess tumor induction in treated groups. The presence of a fourth study with negative results at uncertain dose level does not diminish the Agency's concern that lindane is potentially oncogenic in humans.

Likewise in attempt to rebut the Agency's presumption of oncogenicity, both Hooker Chemicals (30000/10:#42) and Reed and Carnrick Pharmaceuticals (30000/10:#6C) submitted various studies which on the whole indicated no connection between lindane and mutagenic effects.

The Agency rejects these rebuttal attempts for two reasons: 1) mechanisms other than mutation may cause cancer; 2) although for some classes of chemicals there is a high correlation between carcinogenicity in mammalian test systems and mutagenicity in certain microbial systems, this correlation is not absolute, and false positive and false negative indications do occur (EPA 1978a, 1978b). Moreover, three of the mutagenic tests submitted by Hooker Chemicals in fact showed positive results. These positive mutagenic results lend further support to the Agency's original presumption of lindane's oncogenicity (EPA 1978b).

d. Comments Submitted on the National Cancer Institute (NCI) Carcinogenicity Bioassay

Although the NCI preliminary bioassay study on the oncogenic effects of lindane was not a basis for the lindane RPAR, it was mentioned in the RPAR notice, and comments on its significance were solicited. In response, the registrants submitted the NCI final bioassay report, which concluded that the study did not in itself demonstrate that lindane is carcinogenic. (Refer to Table II-1, which compares the results of the NCI study with the results of the three oncogenicity studies cited in the RPAR Notice.)

The Agency rejects this rebuttal effort. While the authors of the NCI bioassay concluded that because of the insufficiency of their data, the bioassay does not constitute sufficient evidence of the carcinogenicity of lindane, it does add to the body of evidence of similar results found in the other three studies in that:

(1) The liver was the target organ. In the NCI study lindane at 80 ppm triggered a highly significant response (hepatocellular carcinoma) in male mice vs. pooled controls (19/49 vs. 5/49; $p = 0.001$). While the high-dose group (160 ppm) did not show a significant increase (9/46 vs. 5/49; $p = 0.10$), there was nevertheless an increase.

(2) Males were more susceptible than females.

In addition to the above similarities, the NCI study provides evidence involving the same target organ in a different strain. The Agency therefore judges that, considered together with the Thorpe and Walker (1973), Goto et al. (1972), and Hanada et al. (1973) studies, the NCI study provides additional evidence of the carcinogenicity of lindane.[5]

2. Attempts to Rebut the Presumption of Reproductive and Fetotoxic Effects

In Position Document 1 the Agency announced a presumption of reproductive and fetotoxic effects on the basis of three lindane feeding studies: Naishtein and Leibovich (1971), Petrescu et al. (1974), and Earl et al. (1973), all of which reported adverse reproductive/fetotoxic responses. The results of each of these RPAR studies are summarized in Table II-2. In response to our request for rebuttal comments and additional information concerning the reproductive and fetotoxic effects of lindane, the Agency received 15 responses from 3 registrants: Hooker Chemicals (30000/10:#42), Franklin Laboratories (30000/10:#37), and Paper Products, Inc. (30000/10:#41).

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[5] The NCI study was terminated after only 90 weeks because of the poor condition of the animals. Since liver tumors are often late appearing, the latent period may not have been long enough to result in the detection of all potential liver tumors from the lindane exposure.

The Agency has reviewed all rebuttal material submitted by the registrants (EPA 1978c) and concludes regarding the original RPAR studies 1) that the Russian studies Naishtein and Leibovich (1971) and Petrescu et al. (1974) have a number of flaws which render them inadequate to completely assess the reproductive effects of lindane and 2) that Earl et al. (1973), which showed that lindane feeding significantly increased the proportion of stillbirths to beagle dogs, stands unrebutted as valid evidence of the fetotoxic effects of the pesticide.

While Earl et al. remains unrebutted as an original RPAR study, several studies which have come to our attention during the rebuttal period reinforce the Agency's concern about the reproductive and fetotoxic effects of lindane. Seven studies submitted in attempted rebuttal by Hooker Chemicals in fact indicate that lindane affects the reproductive performance of the animals tested as well as the condition and/or survival of the fetus.[6/] Two additional studies, Khera et al. (1979) and Trivonva et al. (1970), which the Agency has recently reviewed, provide further indications of lindane-related fetal and reproductive effects.

The Agency's risk assessment of the reproductive and fetotoxic effects of lindane has necessarily focused on fetotoxic effects. (See Subsection II.C, "Risk Assessment.") The quantitative analysis is based on data provided by Khera et al. (1979), Palmer and Lovell (1971), Palmer and Neuff (1971), and Bauer and Frohberg (1972), the latter three studies having been submitted during the rebuttal period by Hooker Chemicals (Table II-3). The Agency was unable to perform a quantitative risk assessment of the general reproductive effects of lindane based on available data.

[6/] These studies (addressed in Subsection II.A.2.e below and summarized in Table II-3) stand as evidence that lindane causes no teratogenic effects in rats, mice, or rabbits. However, the Agency's presumption was based not on teratogenicity, but on general reproductive and fetotoxic effects. An eighth rebuttal study (Table II-3) submitted by Hooker, which indicated only that lindane decreased the growth rate of female pigs prior to mating, did not address the presumption.

Table II-2. Summary of Studies Cited as Bases for the Presumption of Reproductive and Fetotoxic Effects

Species	Protocol	Results	Reference
Mongrel rats	0.05 and 0.5 mg/kg in diet for 4 months prior to mating & pregnancy	Increase in duration of estrous cycle and increased duration of estrous at high dose; no effect of low dose.	Naishtein & Leibovich (1971)
Rats	5, 10, or 15 mg/kg in diet in P, F_1, F_2, & F_3 group	Lengthened avg. duration of pregnancy; decreased fertility index in 15 mg/kg group; retarded sexual maturation & depressed sexual function; progressive increase in proportion of stillbirths in successive generations.	Petrescu et al. (1974)
Beagle dogs	7.5 or 15 mg/kg per day in diet from day 1 or 5 of gestation	Increased frequency of stillbirths in treated animals from 2% in controls to levels of c.18%, 23%, and 30% in dogs ingesting lindane at 7.5 mg/kg/day (beginning on either day 1 or day 5) or 15 mg/kg/day (beginning on day 5) during pregnancy. (No significant teratogenic effects.)	Earl et al. (1973)

The Agency's analysis of the rebuttals submitted regarding the presumption of reproductive and fetotoxic effects is presented in the succeeding Subsections II.A.4.a through e. Additional Agency findings are addressed in Subsection II.A.4.f.

a. Attempted Rebuttals Pertaining to Naishtein and Leibovich (1971)

Two registrants objected to this study. (Refer to Table II-2.) Hooker Chemicals (30000/10:#42) argued that data essential for peer evaluation were not provided. Franklin Laboratories (30000/10:#37) argued that the study was based on an unknown number of test animals.

The Agency acknowledges that the data in the Nashstein and Leibovich study is not presented in sufficient detail and doesn't meet Agency standards in sustaining a presumption. However, even with these deficiencies, the study does provide supportive information on fetotoxicity which strengthens the conclusions reported in the Earl et al. study and other studies (see Section II.2.e.).

b. Attempted Rebuttal Pertaining to Petrescu et al. (1974)

Hooker Chemicals (30000/10:#42) argued that Petrescu et al. (Table II-2) did not meet currently acceptable scientific standards: 1) there was no discussion of toxic effects in dams; 2) there were too few test animals per group; 3) the study was unusual in design (pregnancies were repeated over the animals' lifetime for the F_o generation); 4) there was no information on anticipated normal pathology in experimental or control groups; and 5) the fertility index appeared to be unusually low for all groups, including control groups.

This rebuttal is accepted (EPA 1978c). The Agency acknowledges that Petrescu et al. shows deficiencies in design and fails to provide sufficient data so that the reported findings can be adequately judged.

The Petrescu study did show effects on fetotoxicity at doses below those established for causing acute and subacute effects (5 mg/kg). The presence of a second study (Palmer et al., 1972) (see Table II-3) reporting no effects does not detract from Petrescu's reported results. However, the Palmer study does reduce the strength of the Petrescu study and accordingly the Agency will not attempt to use Petrescu as the sole support of the fetotoxicity presumption, although the Agency will use Petrescu's results as supportive information in evaluating the risk of fetotoxicity.

c. Attempted Rebuttals Pertaining to Earl et al. (1973)

Two registrants objected to this study. (Refer to Table II-2.) Hooker Chemicals (30000/10:#42) argued that the study was invalid in that 1) it lacked sufficient information for evaluation and 2) it used

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non-concurrent controls. In addition, Hooker cited a 32-week study in non-pregnant beagles (Noel, 1970) which indicated that lindane (200 ppm dietary intake) caused toxic effects at doses as low as 5 mg/kg per day. Franklin Laboratories (30000/ 10:#37) argued that the apparent increase in the incidence of stillborn animals from lindane feeding was inconclusive because a 7.5 mg/kg dose produced 30.5 percent stillborn, while double that dose produced only 17.9 percent stillborn (a reduction of nearly half).

The Agency rejects these rebuttal attempts (Memo 1978a; 1978b). The Earl et al. study was published in 1973, and data from the concurrent controls were generated from January 1970 through October 1972. Earl et al. provided data from several control groups, at least one of which is clearly "concurrent" with the test groups. For this control group, the percentage of stillborn pups was 5.7 percent, as compared to 30.5 percent stillborn in the 7.5 mg/kg group. The beagle study (Noel, 1970) cited by Hooker is not inconsistent with the observation of fetotoxic effects in beagles at higher doses by Earl et al. (1973). The apparent lack of a dose-response relationship does not invalidate the observed increases of stillborn animals in treated groups as compared to controls.

d. Attempted Rebuttals Pertaining to Exposure: Fetotoxicity

For chronic effects risk criteria such as fetotoxicity, Agency regulations require the Administrator to determine whether the effect occurs at a dose level "substantially higher than that to which humans can reasonably be anticipated to be exposed, taking into account ample margins of safety" [40 CFR 162.11(a)(3)(ii)(B)]. As Position Document 1 stated, "In the absence of an established level at which there was no demonstrated effect and with a subsequent lack of basis for choice of an 'ample margin of safety,' it may be presumed that current exposure is sufficient to produce reproductive and fetotoxic effects in humans" (EPA 1977a).

Only one respondent specifically addressed the issue of ample margins of safety. Paper Products, Inc. (30000/10:#41) construed the applicable passage of 40 CFR (cited above) to mean that the Administrator must make a specific determination of an ample margin of safety and argued that, "unable to meet the evidentiary standards of its own regulations, the EPA has simply dispensed with them." The registrant noted in this context that its product (shelf paper) contains 15 mg of lindane per square foot and argued that, using the smallest doses cited in Position Document 1 (0.5 mg/kg), a pregnant woman would have to ingest 2 square feet of the product per day for four months to obtain a dosage comparable to that used in Naishtein and Leibovich.

The Agency rejects the registrant's interpretation of Agency regulations. The "evidentiary standards" of Agency regulations are addressed in the Subsection II.C.2 of this document, which establishes a no observable effect level and discusses margins of safety for fetotoxic effects from lindane exposure. The Agency points out also that the principal route of exposure to this product is inhalation of lindane vapor

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released from shelf paper. [See Subsection II.B.2.m.(1).] In its risk assessment of lindane shelf-paper products, the Agency does not consider ingestion to be an anticipated route of exposure.

e. Additional Studies Submitted in Attempted Rebuttal

In attempt to rebut the presumption of reproductive and fetotoxic effects, Hooker Chemicals (30000/10:#42) submitted the following seven studies which indicated no connection between lindane and teratogenic effects in mice, rats, or rabbits: two mouse studies by Bauer and Prohberg [1972 (confidential; unpublished)], one in which lindane was administered via stomach tube and one in which lindane was injected subcutaneously; a rat study by Palmer and Lovell [1971 (confidential; unpublished)] in which lindane was administered by intubation; a rabbit study by Palmer and Neuff [1971 (confidential; unpublished)] in which lindane was administered via intragastric intubation; a 3-generation rat study by Palmer et al. [1972 (confidential; unpublished)] in which lindane was administered in the daily diet; a rat study by Reno [1976 (confidential; unpublished)] in which lindane was injected subcutaneously; and a rabbit study by Reno [1976 (confidential; unpublished)] in which lindane was injected subcutaneously. Hooker also submitted an eighth study, a French study by Duee et al. (1975), in which female pigs were administered lindane in the daily diet. Lindane apparently had no effect on the weight gains of the sows during the first month of gestation or on their rate of ovulation, and the number of embryos and their weight were likewise reported unaffected. Table II-3 summarizes these eight studies.

The Agency rejects these rebuttal efforts (EPA 1978c; memo 1978a, 1978b). Regarding the rat, mouse, and rabbit studies, the Agency grants that no teratogenic effects (birth defects) were observed. However, it must be emphasized that teratogenic effects are not at issue. The Agency's original presumption was based not on teratogenicity but on general reproductive or fetotoxic effects. Fetotoxic effects were in fact observed in the submitted studies at or near (both below and above) doses that caused maternal toxic effects.

The Agency has reviewed Duee et al. (1975) in translation and finds that although no overt fetotoxic effects were observed, a lack of data in the paper undermines the usefulness of the study. However, while the Duee study cannot be used for establishing and providing sole support of a presumption, the study does provide information on lindane's adverse effects and adds to that body of knowledge.

f. Additional Agency Findings Concerning the Presumption of Reproductive and Fetotoxic Effects

In addition to the eight studies submitted during the rebuttal period by Hooker Chemicals, Agency research has discovered two further studies, Khera et al. (1979) and Trivonva et al. (1970 [reviewed in abstract]) of the reproductive and fetotoxic effects of lindane on rats.

Table II-3. Summary of Studies Submitted in Attempt to Rebut the Presumption of Reproductive and Fetotoxic Effects

Species	Exposure Route	Duration of Exposure	Dose	Results	Reference
NMRI mice	Subcutaneous	Days 6-15 & 11-13 of gestation	6 mg/kg daily	Percent abortions, early & late resorptions, mean fetal length, & sex ratio in test groups comparable to controls. Statistically significant increase in # of congenital runts in day 6-15 group; 6 of 7 runts were from same liter. No teratogenic or maternal toxic effects observed.	Bauer and Frohberg [1972 (Confidential; unpublished)]
NMRI mice	Stomach tube	Days 6-15 & 11-13 of gestation	12, 30, 60 mg/kg daily	In day 6-15 group at 60 mg/kg, # of abortions significantly increased, mean # of fetuses lower than in control groups; mean fetal weight significantly reduced as compared to controls receiving carrier/vehicle; this increase was significant compared to entire control group. The increase in abortions at 12 mg/kg/day (days 11-13) may not be lindane-related since the effect was not seen in the group fed 12 mg/kg on days 6-15 nor in the groups fed 30 mg/kg and 60 mg/kg on days 11-13. Maternal toxic effects observed at 60 mg/kg; none at 30 or 12 mg/kg.	Bauer and Frohberg [1972 (Confidential; unpublished)]

Table II-3. Summary of Studies Submitted in Attempt to Rebut the Presumption of Reproductive and Fetotoxic Effects (Cont.)

Species	Exposure Route	Duration of Exposure	Dose	Results	Reference
Female Specific Pathogen Free Rats	Intubation	Days 6-15 & gestation	0, 5, 10 20 mg/kg daily	Food consumption and maternal weight gain were decreased at the 2 higher doses. Statistically significant increase in skeletal variation (extra ribs) at high dose. Possible increase in extra ribs at middle dose. NOEL for fetal and maternal effects 5 mg/kg/day.	Palmer and Lovell [1971 (Confidential; unpublished)]
New Z. white rabbits	Intragastric intubation	Days 6-18 of gestation	0, 5, 10 20 mg/kg daily	All treated animals showed increased respiration and drowsiness and decreased weight gain; # of animals which conceived slightly lower at 10 & 20 mg/kg. Statistically significant decrease in 13-ribbed pups at 5 mg/kg and an increase at 20 mg/kg. Since in rabbits the normal # of ribs is 12 pairs, the effects at 5 mg/kg are not adverse.	Palmer and Neuff [1971 (Confidential; unpublished)]

Table II-3. Summary of Studies Submitted in Attempt to Rebut the Presumption of Reproductive and Fetotoxic Effects (Cont.)

Species	Exposure Route	Duration of Exposure	Dose	Results	Reference
Charles River Rats	Diet	Continuous for 3 generations	0, 25, 50, or 100 ppm daily	No adverse effects in parental generation. No effects on litter mortality, size, and weight or mean pup weight from birth to 21 days post partum. Mean absolute liver weights in high dose males and females of F-3b generation significantly increased ($p<0.01$) compared to controls. Mean relative organ weights significantly increased ($p<0.001$) in high-dose males. Female liver/body weight significantly increased in females at all doses ($p<0.001$ at high dose). Enlarged hepatocytes increased in 50 and 100 ppm groups. Gestation index in F-0b litter was 98.9% in controls and 92.7% in high-dose group (due to 13 of 15 stillborn litter).	Palmer, Cozens, Lovell et al. [1972 (Confidential; unpublished)]
Rats	Subcutaneous injection	Days 6-15 of gestation	0, 5, 15 30 mg/kg daily	All doses caused an increase in fetuses having an extra rib when compared to controls. NOEL for maternal effects is 5 mg/kg; mater- (cont.)	Reno [1976 (Confidential; unpublished)]

Table II-3. Summary of Studies Submitted in Attempt to Rebut the Presumption of Reproductive and Fetotoxic Effects (Cont.)

Species	Exposure Route	Duration of Exposure	Dose	Results	Reference
Rats (Cont.)				nal toxicity observed in two high dose groups. No teratogenic effects observed in fetuses.	Rano (Cont.)
Rabbits	Subcutaneous injection	Days 6-18 of gestation	0, 5, 15 mg/kg; high-dose group: 45 mg/kg, days, 6-9, & 30 mg/kg, days 10-18	No embryotic or teratogenic effects in 5 & 15 mg/kg fetuses. Maternal toxicity observed in 15 and 45-30 mg/kg groups. High-dose fetuses not examined for teratogenic effects due to high incidence of maternal toxicity. Statistically significant incidence of resorptions observed at 45-30 mg/kg.	Rano [1976 (Confidential; unpublished)]
Female pigs	Diet	30 days prior to mating and 30 days of gestation	0.50 and 500 ppm daily	Both doses apparently decreased growth rate prior to mating. No effects on weight gain during first month of gestation nor on # of embryos, embryo weight, or rate of ovulation.	Duee et al. (1975)

Khera et al. (1979) administered orally a 50 percent lindane formulation, Benesan, to pregnant rats from day 6 through 15 of gestation.[7] The doses used were 6.25, 12.5, or 25 mg/kg/day of the formulation, corresponding to approximately 3.15, 6.25, or 12.5 mg/kg/day technical lindane. Although maternal body weight data were not given, the authors reported that the average maternal body weight for the high-dose group decreased on day 15 and at necropsy, though this decrease was not considered statistically significant. There was no compound-related effect on incidence of live fetuses, dead plus resorbed fetuses, or mean fetal weight, and the incidences of anomalous litters and individual anomalies were similar to controls. There was, however, an apparent increase in the number of fetuses having wavy and extra ribs and delayed ossification of calvarium in the mid-dose group. This increase was not tied to a significant increase in the number of litters with anomalous fetuses per the number of litters examined, but rather was the result of large numbers of affected fetuses within fetus litters. Effects analogous to those observed at the mid-dose level were not observed at the high-dose level (12.5 mg/kg/day) though slight maternal toxic effects were evident at this dose.[8]

Trivonva et al. (1970) fed lindane to female rats for 90 days at 5 mg/kg/day and for 138 days at 10 mg/kg/day. No reproductive effects were observed at the lower dose, whereas the higher dose caused a reduction in litter size and fecundity.

3. Comments Submitted on the Presumption of Acute Toxicity to Wildlife: Aquatic Organisms

In Position Document 1, the Agency cited studies showing that application of greater than 0.000116 pounds/acre of lindane to a 6-inch layer of water would exceed one half the 96-hour LC_{50} for pink shrimp, a marine/estaurine species having the lowest LC_{50} among representative species. Also cited were studies showing that application of greater than 0.00273 pounds/acre of lindane in a 6-inch layer of water would exceed one half the 96-hour LC_{50} for brown trout, a fresh-water species having the lowest LC_{50} among representative species.

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[7] Khera et al. are employed by the Bureau of Chemical Safety, Canadian Government. Benesan was obtained through Chipman Chemicals Ltd., Stoney Creek, Ontario.

[8] Because of the uncertain pattern of the results reported by Khera et al. (no dose-response was established, and the effects observed at 6.25 mg/kg/day were relatively slight), the Agency has for risk assessment purposes considered the no observable effect level (NOEL) of this particular study to be 12.5 mg/kg/day as the authors concluded. (See Section II.C.2.)

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The Agency received no rebuttals to this presumption of risk. However, the United States Department of Agriculture (30000/10:#13) commented that in the USDA Forest Service's "operational use of lindane, precautionary measures are taken to ensure that the spray does not directly, or indirectly, get into streams." Likewise, Hooker Chemicals (30000/10:#42) submitted that "lindane should not be applied directly to water."

The Agency points out that the original presumption of acute toxicity to aquatic organisms was issued even though no known lindane products remain registered for aquatic uses 1) to insure that all lindane products with label directions for aquatic use would be acted upon, and 2) to address registered non-aquatic uses which -- via means such as drift or runoff — might result in lindane-contaminated aquatic environments. Because no lindane products are currently registered for direct aquatic application, the presumption is hereby withdrawn. The Agency remains concerned, however, about the possibilities of drift or runoff should any non-aquatic lindane product be misused.

4. Comments Submitted and Agency Findings on Possible Adverse Effects

In addition to initiating presumptions on oncogenicity, reproductive and fetotoxic effects, and acute toxicity to aquatic organisms, the Agency requested additional evidence in situations where it had reason to believe risk concerns were present. The Agency sought information both in situations where additional information could assist the Agency in determining where its risk criteria were met and in situations, where the potential of unreasonable adverse effects, outside the triggers, were presented.[9] The Agency has chosen to treat significant risk information not anticipated by current risk triggers as giving rise to risk concerns that are appropriately handled within the framework of the RPAR process and is therefore including this type of risk information in this Position Document.

The effects where the Agency sought additional information include (1) mutagenicity, (2) blood dyscrasias (3) acute toxicity hazard to humans and domestic animals, and (4) population reductions in non-target avian species. The Agency also requested registrants and other interested persons to submit information on the possible isomerization of gamma - BHC (lindane to alpha - or beta BHC, which have been shown to be oncogenic in rodents. The succeeding subsections treat the potential adverse effects listed above, and give the Agency's assessment of the information received and its additional findings conerning these effects.

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[9] In situations where a pesticide's use presents unreasonable risks not covered by the RPAR criteria, Section 162.11(a)(6) provides that the Agency may commence cancellation proceedings. However, where the Agency is issuing a proposed RPAR decision document, it is in the public interest for the Agency to include all risk concerns bearing on registrability in this document, including additional risk information outside the RPAR triggers.

a. Studies Submitted on Possible Adverse Effects: Mutagenicity

In Position Document 1 the Agency cited several investigations of lindane's mutagenic capacity and concluded that existing data did not establish that lindane is a mutagen, and that risk criteria warranting a rebuttable presumption had not been met. Additional information on this area of concern was solicited, however, and during the rebuttal period, two registrants, Hooker Chemical Co. (30000/10:#42) and Reed and Carnrick Pharmaceuticals (30000/10:#6C), submitted several studies (Table II-4) on the mutagenic potential of lindane, all of which have been reviewed by the Agency (EPA 1978C). Although lindane triggered positive mutagenic responses in two metabolic activation tests and one host-mediated assay with S. typhimurium, negative mutagenic results were observed in one metabolic activation test with S. typhimurium, two dominant lethal studies in rats, and one cytogenetic analysis of Chinese hamster bone narrow.

The Agency has also reviewed a report by Ishidate and Odashima (no date) of a cytogenetic assay in Chinese hamster fibroblasts, in which the authors observed gaps and breaks occurring at the high dose. In evaluating this study, the Agency found that the occurrence of breaks was not statistically significant. The reported observations of gaps and breaks at a dose which appeared to produce cytotoxicity and in the absence of a dose-effect relationship, do not support a presumption of mammalian mutagenic potential.

The Agency has reviewed and evaluated all data which have become available since PD 1 was issued (EPA 1978a; EPA 1978b; EPA 1978c). In view of the test results outlined above and in Table II-4, the Agency reaffirms its original position that on the basis of available evidence no presumption of mutagenicity is justified at this time. However, because indications of mutagenesis constitute indirect evidence of carcinogenicity, the positive responses observed in several studies have bearing on the Agency's presumption of oncogenicity (EPA, 1979). The presumption of oncogenicity is thereby qualitatively reinforced.

b. Comments Submitted and Additional Agency Findings on Possible Adverse Effects: Blood Dyscrasias

In Position Document 1 the Agency cited several case studies which indicated that aplastic anemia, hypoplastic bone marrow, and other blood dyscrasias in humans were associated with exposure both to lindane alone and to lindane in combination with other chemicals. Additional information was solicited. The Agency pointed out in PD1 that the medical case histories cited did not satisfy epidemiologic criteria for establishing a cause-effect relationship between lindane exposure and blood disorders. However, the Agency was, and is, concerned that differences in sensitivities may create a subgroup of the population which might be more than ordinarily susceptible to possible lindane-related blood dyscrasias. In this connection the Agency is especially concerned about cases of exposure to children.

Table II-4. Summary of Studies Submitted on Lindane as a Possible Mutagen

Rebuttal * Reference	Study Type	Species & Strain	Doses	Results
Van Dijck & Van de Voorde (1976); #42 (Vol. IV, Sec. 36)	Ames test (metabolic activation with mouse liver microscmes); Dose-response test with activation	*S. typhirmurium*, TA 98, 100, 1535, 1537, 1538, 1950, 1978	1 & 1,000 ug/plate; 1, 10, 100, & 1000 ug/plate	No DNA killing or reversion to prototrophy; No mutagenic potential
Rano (1976) #6 (pp. 104-118)	Dominant lethal	Sprague-Dawley rats	0, 1, 3, & 10 mg/kg daily, subcutaneous injection for 10 weeks	Significant increase in dead implants at week 1 appeared to be function of statistics & low control values; no dose response
Rohrborn (1975); #42, (Vol. V, Sec. 39)	Ames test (metabolic activation with mouse liver microscmes)	*S. typhimurium*, TA 1535, & 1538	0.3125, 0.625, 1.25, 2.5, & 5 ug/plate	Probable base-pair substitution (TS 1535); highly significant increased frequency of frame shift mutation (195X) in TA 1538
Rohrborn (1977); #42, (Vol. V, Sec. 40)	Ames test (metabolic activation with mouse liver microscmes)	*S. typhimurium*, TA 100, 98, 1535, & 1538	93, 139, & 208 ug/plate	Slight bacteriostatic effect; 2.59X increase mutation in TA 1535; 2.72X increase in TA 1539 at highest dose

*All rebuttal references cited carry the prefix 30000/10.

Table II-4. Summary of Studies Submitted on Lindane as a Possible Mutagen (Cont.)

Rebuttal Reference*	Study Type	Species & Strain	Doses	Results
Rohrborn (1976); #42, (Vol. V, Sec. 41)	Host activation (male NMRI mice)	*S. typhimurium*, TA 1535	0.5, 5, & 50 mg/kg	8.78X increased mutation at highest dose
Rohrborn (1976); #42, (Vol. V, Sec. 42)	Cytogenetic bone marrow analysis	Male & female Chinese hamsters	0.125, 1.25 & 12.5 mg/kg for 5 days	No significant responses; doses were 10, 100, & 1,000X ADI for humans
Rohrborn (1977); #42, (Vol. V, Sec. 43)	Dominant lethal**	Male rats	1.5, 7.0 & 15 mg/kg per day for 8 weeks	None
Carey et al., 1975	Dominant lethal	Male rats	1.5, 7.0 & 15 mg/kg per day for 8 weeks	Reported as positive**

*All rebuttal references cited carry the prefix 30000/10.

**The Carey et al. study was reported as positive, but no supporting data was included in the publication. The Agency also could not obtain the necessary information from the authors. Therefore, while the authors claim this study to be positive, without the substantiating data, the Agency will not attach any significant strength to this study.

Concerning blood dyscrasias as a possible adverse effect of lindane, the Agency received 16 responses from four registrants: Hooker Chemicals, Franklin Laboratories, Paper Products, Inc., and Reed and Carnrick Pharmaceuticals. Six of the submissions (30000/10:#4A; #4B; #4C #18A; #41; #42) were indeterminate as to whether there exists a cause-effect relationship between lindane exposure and blood dyscrasias in humans. Of those six submissions, three argued that exposure from specific lindane products was so low that no risk is involved. Another four submissions from Hooker Chemicals (30000/10:#42), which attempted to show that lindane does not cause blood dyscrasias in humans, could not be evaluated because supporting data were either absent or insufficient. In addition, however, Hooker submitted six studies surveying various human populations for a relationship between lindane and blood dyscrasias. These six surveys lend support to the Agency's original determination that there is insufficient epidemiologic evidence to establish such a cause-effect relationship.

In addition to the material submitted by registrants, further data on lindane and blood dyscrasias have come to the Agency's attention since PD1 was issued. Specifically, the Agency is aware of two in-progress epidemiological studies in Iowa and Illinois and in Hawaii, respectively, the first of which was prompted by a clinical incident linking lindane and a child's blood disorder. The case in question involved a 32-month-old Illinois boy who was diagnosed as suffering from aplastic anemia secondary to lindane exposure and led to an epidemiological study of exposed households in Iowa and Illinois by the Iowa Epidemiological Study Center.

Lindane was present in the child's blood at 1.6 ppb.[10] Analysis of the blood of other family members showed the following levels of lindane: father, 4.9 ppb; mother, 3.1 ppb; and sister, 8.1 ppb. A lindane vaporizer in the house had been operating continuously since 1970. It was discovered that the distributor of this product sold lindane vaporizer crystals on a continuing basis, servicing homes and businesses at about 375 locations in Illinois and Iowa during 1978.

As a result of these findings, the Iowa Epidemiologic Study Center has undertaken a special study of 478 people in private homes in Iowa and Illinois who had been exposed to lindane in connection with home-use vaporizers for varying lengths up to 26 years. Because lindane is absorbed in many exposed surfaces during vaporizer use, then revolatized from these surfaces into the air, exposure to lindane extends beyond the time of actual operation of the vaporizer. The Agency has received some preliminary, statistically unchecked results of this study. In the 235 households surveyed, 440 blood samples were taken and analyzed for lindane and chlorinated hydrocarbons. Approximately 70 percent of these samples contained lindane ranging from 1 to 46 ppb. Air samples were taken in 10 percent of the homes, and lindane was found in the air in every home.

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[10] Another recent incident indicative of the particular sensitivity of children to the potential effects of lindane is addressed in connection with acute central nervous system effects [Subsection II.A.4C(4)(c) below]. The case in question involved the death of a two and one half month old infant who had been treated for scabies with a commercial lindane product.

A total of 478 health questionnaires have also been compiled. Because the study remains to be completed, the final results of the Iowa study will be presented in Position Document 4.

The second epidemiological study, currently being conducted in Hawaii, was prompted by the occurrence of five cases of aplastic anemia in Maui County (population: approximately 50,000), a relatively high incidence given that aplastic anemia is generally considered a rare disorder (national mortality rate: 0.1/100,000). The Agency has reviewed protocol and progress reports and has telephone interviewed the Hawaii Project Director of this study (Memo 1980a). The 2-year study is designed to detect blood dyscrasias associated with a wide range of organochlorine pesticides, including lindane. Data are being gathered on patients with diagnoses of aplastic anemia, agranulocytosis, and blood dyscrasias. The approach of the study is as follows: 1) to obtain lists of patients with the abovenamed diagnoses, 2) to solicit statewide cooperation from all family practitioners, pathologists, and hematologists, 3) to administer questionnaires to patients concerning pesticide usage - home and occupational usage, and 4) to review medical records, both hospital and out-patient, for demographic and pertinent clinical data. The results of this study will not be available until the end of the 1980 calendar year, and the Agency is at this time unable to judge whether or not the study will prove useful in terms of establishing or disproving a causal relationship between lindane and blood dyscrasias. The Agency has been advised, however, that "there is no evidence which focuses attention on lindane at this time." The final results of the Hawaii epidemiology study will be presented and evaluated together with the results of the Iowa study in Position Document 4.

Taking into account all currently available data, the Agency must reaffirm its original position that insufficient evidence exists to firmly establish a cause-effect relationship between lindane exposure and blood dyscrasias. The Agency points out, however, that the epidemiological data submitted do not satisfactorily answer the very complex question of whether the hematopoietic tissues of certain individuals, particularly children, might be peculiarly sensitive to lindane.

c. Comments Submitted and Agency Findings on Possible Adverse Effects: Acute Hazards to Humans and Domestic Animals

In Position Document 1, the Agency cited 99 health-related incidents recorded by the EPA Pesticide Episode Reports System (PERS) between 1966 and 15 June 1976 which implicated products containing lindane. In that connection registrants were requested to submit any data they might have on the acute toxicities, both dermal and inhalational, of their lindane products, including products formulated with other active ingredients.[11/]

[11/] "Episodes" include all association with a given pesticide and do not always imply ingestion. The PERS data do not necessarily include all incidents which have occurred during the given time span.

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Eighty-four of the incidents cited in PD1 involved humans, and the majority of these occurred in the home. Fifteen involved domestic animals. Of the 84 human incidents, 49 involved lindane as a sole active ingredient, and 35 listed lindane in combination with another active ingredient. The majority of the lindane-only cases involved children (in 24 cases the child ingested the pesticide) and half of the lindane-only episodes led to clinical symptoms. Hospitalization followed by death occurred in five of the episodes. The majority of the incidents attributed to lindane in combination with another pesticide involved adults. Clinical symptoms were cited in less than half of these episodes, and two cases resulted in death. Fifteen livestock or domestic pet incidents were reported, nine involving lindane as a sole active ingredient and six involving lindane in combination with another active ingredient.

The submissions received during the rebuttal period are addressed in Subsections (1) through (3) below. These comments did not mitigate the Agency's concerns over lindane exposure. In addition to the studies submitted by registrants and in addition to the evidence which was cited in PD1, data have come to the Agency's attention which show that exposure to lindane, both in test animals and in humans, can cause adverse effects manifest in particular as symptoms of central nervous system (CNS) stimulation. In this connection there is evidence also to suggest that children are especially sensitive to the acute toxic effects of lindane. Additional Agency findings concerning the acute effects of lindane as a CNS stimulant are presented in Subsection (4) below. The Agency's assessment of the acute and subacute toxic risk of lindane is given in Subsection II.C.3.

(1) Acute Hazards: Studies Submitted on Inhalation Toxicity

Two registrants, Chevron Chemical Co. and Reed and Carnrick Pharmaceuticals, submitted data intended to demonstrate that lindane poses no acute inhalation toxicity. Chevron (30000/10:#38) submitted a study in which groups of five male and five female Sprague-Dawley rats were each exposed for one hour to about 50 mg/liter vapor and 75 mg/liter aerosol of a commercial lindane product. Although the animals were ataxic after one hour of exposure to the vapor, they recovered within 24 hours. No toxicity or deaths resulted from exposure to the aerosol. Test rats in both groups showed weight gains comparable to controls. At autopsy, no gross pathological changes were attributable to lindane. This study has been reviewed by the Agency (EPA 1978c). The exposure chamber ("tunnel chamber") was neither described nor referenced to existing literature. No data were given on uniformity of distribution of the test material, chamber temperature, humidity, or handling conditions of the animals. No raw data to substantiate the study's findings were provided.

In an effort to show that lindane presents no respiratory hazard, Reed and Carnrick (30000/10:#6C) submitted an acute inhalation toxicity study in rats. Five male and five female adult rats were exposed for one hour in a 40-liter glass chamber to a concentration of 12.8 mg lindane/liter [sic, Agency calculation = 14.4 mg/liter]. No toxicity or positive pathological findings were observed after the 14-day observation period. The Agency has reviewed this study and considers it invalid (EPA 1978c) for the following reasons. The chamber, the generating system, and the exposure conditions were not adequately described. Nor did the authors state whether the (undescribed) atomizer, used to introduce the test material into the chamber, produced respirable particles. Data given in the study do not provide information on the LC_{50} dose-response.

(2) Acute Hazards: Studies Submitted on Dermal Toxicity

Two registrants, Reed and Carnrick Pharmaceuticals and Chevron Chemical Co., submitted a total of five studies on the dermal toxicity of lindane. Reed and Carnrick (30000/10:#6C) submitted four studies on lindane as a scabies treatment. Three of the studies, Woolridge (1948), Halpern et al. (1950), and Korneblee and Combes (no date), involved human patients, none of whom experienced side effects when treated with lotion formulations containing from 0.15 percent to 1 percent lindane. The fourth study, Mohrmann (1976), involved rats which were treated with a commercial lindane-formulated lotion sold for human use. At autopsy, none of the rats showed gross pathological effects. The Agency has evaluated these studies (EPA, 1978c). Two of the studies performed on human patients, Halpern et al. (1950) and Woolridge (1948) were found valid. The third epidemiological study, Korneblee and Combes (undated), provided insufficient data for Agency validation. The fourth study, Mohrmann (1976) on rats, was likewise found valid (EPA, 1978c).

Chevron Chemical Co. (30000/10:#38) submitted a study on the dermal toxicity of a commercial lindane spray product to adult male rabbits showing an LD_{50} of 922 mg. a.i./kg. The Agency has reviewed this study and considers it valid (EPA 1978c).

In addition to the five studies outlined above, the Agency received from Hooker Chemicals (30000/10:#42C) a tabulation of data for acute toxicity in rats, primary skin irritation in rabbits, and primary irritation of rabbit eye mucosa. Because experimental procedures were not included, the Agency was unable to determine the validity of these data. However, the EPA scientists who reviewed the material noted that it was "in general agreement with other similar studies" (EPA 1978c).

(3) Acute Hazards: Studies Submitted on Oral and Intraperitoneal Toxicity

Hooker Chemicals (30000/10:#42C) submitted a study on acute toxicity in rats following oral and intraperitoneal administration of lindane. Rats were incubated with aqueous suspensions of lindane at doses ranging from 64 to 400 mg/kg, and intraperitoneally injected with aqueous suspensions of lindane at doses ranging from 32 to 125 mg/kg. The Agency has reviewed this study and considers it valid (EPA 1978c). The LD_{50} for both exposure routes was determined for days 1, 7, and 14 after application. The LD_{50} for intraperitioneal injections was 69 mg/kg for all three days; for incubation, the LD_{50} for 1 day was 176 mg/kg; for days 7 and 14, the LD_{50} was 163 mg/kg.

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(4) Acute Hazards: Additional Agency Findings Concerning Central Nervous System Stimulation

Since the publication of the lindane RPAR notice and PD1, additional data have come to the Agency's attention which show that exposure to lindane, in humans and in laboratory animals, can cause symptoms of acute poisoning which are typical of central nervous system (CNS) stimulation. See Table II-5.

Peripheral nervous system involvement is described in studies by Dallemagne et al. (1950), White and Larrabee (1973), and Schwarz and Kaschowitz (1968). These studies describe degeneration of neurons, acting as a sympathetic ganglionic blocking agent, and lowered excitability of the retina from exposure to lindane (Memo Undated b). Studies by St. Omer (1971) and Desi (1974) also showed CNS involvement leading to seizures, convulsions, and learning impairment.[12/]

Symptoms in the animals appear in the following order: 1) increased respiratory rate, 2) restlessness, 3) intermittent muscle spasma, 4) salivation, 5) disequilibrium, 6) convulsions, 7) collapse, and 8) death.

Symptoms of acute human poisoning are similar to those displayed by laboratory animals and appear in this order: 1) dizziness, 2) headache, 3) nausea and vomiting, 4) diarrhea, 5) tremors, 6) weakness, 7) convulsions, 8) dyspnea, 9) cyanosis, and 10) circulatory collapse. When tested in humans, the following results were obtained with the 100 percent gamma isomer (Hayes, 1963): 40 mg/day (.66 mg/kg/day) x 14 days - no effect; 45 mg three times daily x 3 days (2.3 mg/kg/day) - no effect; 180 mg/day repeated (3 mg/kg/day) - dizziness and diarrhea after several days.

(5) Heightened Susceptibility of Children to Lindane Poisoning

The Agency is concerned in particular about the potential for lindane to produce acute effects in children,[13/] as

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[12/] While not directly demonstrating effects to the CNS, Koransky and Ullberg (1964) demonstrated that lindane was distributed in the CNS 24 hours after administration. The radioactive lindane used in this study was found almost exclusively in brain structures containing white matter (Memo Undated b).

In a second study, Litterst and Miller (1975), after 60 minutes i.v. infusion of lindane in dogs, found lindane in the white matter and, to a lesser degree, in grey brain matter. These studies add significant weight to the reported CNS effects.

[13/] Even though it may not meet the acute toxicity trigger, this risk factor is being treated by the Agency as part of the regulatory equation.

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Table II-5. Acute Effects: Summary of Human and Animal Studies on Lindane as a Central Nervous System Stimulant

Animals				Humans		
References	Species	Dosage	Results	References	Dosage	Results
Desi (1974)	Wistar R rats, male and female	2.5 mg/kg/day x 40 days	After 22 days, decreased performance on a Skinner box feeding test was noted (due to increased irritability). No other changes were noted.	Hayes, (1963)	(10-30%) 40 mg/day x 10 days (oral)	Approximate equivalent of 0.7 mg/kg/day yielded diarrhea after 8th day
		5 mg/kg/day x 40 days	Decreased performance in Skinner box tests and maze running tests. Slight increase in kidney weight and some brain hemorrhage noted at autopsy.		(60-85%) 40 mg/day x 14 days (oral)	Approximate equivalent of 0.7 mg/kg/day yielded no observed effect
					110 mg/day repeated (oral)	Approximate equivalent of 1.9 mg/kg/day yielded diarrhea after 6th day
		10 mg/kg/day x 40 days	As at 5 mg/kg/day		(100%) 40 mg/day x 14 days (oral)	Approximate equivalent of 0.7 mg/kg/day yielded no observed effect
		50 mg/kg/day x 40 days	Decreased body weight gain rate, spleen enlargement, and increased liver weights noted at autopsy - greatly decreased performance in Skinner box and maze running tests.		45 mg 3 times daily x 3 days (oral)	Approximate equivalent of 2 mg/kg/day yielded no observed effect
					100 mg/day repeated (oral)	Approximate equivalent of 3 mg/kg/day yielded dizziness and diarrhea after several days

Table II-5. Acute Effects: Summary of Human and Animal Studies on Lindane as a Central Nervous System Stimulant (Cont.)

Animals				Humans		
References	Species	Dosage	Results	References	Dosage	Results
Schwarz and Kasuhovits (1968)	2 species of frogs	3 mg/animal	Measurements of flicker fusion frequencies in an electroretinogram showed that lindane decreased the efficiency of the visual process at different light intensities and colors. CNS excitability was confirmed by accompanying increases in amplitudes of responses in these tests. (Sensitivity of the nerves increased but efficiency or speed decreased).			
White and Larrabee (1973)	Adult, female Charles River rats	*in vitro* incubation of ganglia	Action potential in postganglionic nerve (after stimulation of preganglionic nerve) decreased markedly when lindane was present (up to 0.1 mM). Complete synaptic blockage was achieved. Reversibility was also demonstrated.			

Table II-5. Acute Effects: Summary of Human and Animal Studies on Lindane as a Central Nervous System Stimulant (Cont.)

Animals				Humans		
References	Species	Dosage	Results	References	Dosage	Results
Hanig et al. (1976)	Adult male New Zealand rabbits	1% dermal				
		60 mg/kg - shaved, depilated, stripped	2 of 4 animals showed increased excitability. There were no deaths or convulsions.			
		- shaved	No observed effects			
	Weanling male New Zealand rabbits	60 mg/kg - shaved, depilated, stripped	Excitement in all; 4 of 6 died.			
		- shaved, depilated	Excitement in all animals; 50% death.			
		- shaved	Excitement and convulsion in 2 of 6; no deaths.			
Koransky and Ullberg (1964)	Female rats	i.p.	Injection of 200 mg/kg with ^{14}C-BHC showed clear localization in brain white matter (after 24 hours), and in sections rich in myelin fibers.			

Table II-5. Acute Effects: Summary of Human and Animal Studies on Lindane as a Central Nervous System Stimulant (Cont.)

Animals				Humans		
References	Species	Dosage	Results	References	Dosage	Results
Litterst and Miller (1975)	Male beagle dogs	(i.v.) 2.4 mg/kg with or without pre-treatment with pheno-barbital	The study showed preferential accumulation in brain structures - white matter. Pretreatment (60 days) with 35 mg/kg/day phenobarbital decreased levels of lindane in brain (no change in blood levels) and decreased events of seizure.			
St. Omer (1970)	Female rats and cockerels	(i.v.) 11.5 mg/kg	After infusion of lindane, high levels of ammonia existed in brain tissue.			
			Lindane was found to be more toxic than dieldrin, heptachlor or DDT.			
Dallemagne et al. (1950)	Dogs	(i.p.) 10 to 30 mg/kg/injection (total doses 130 to 475 mg/kg)	After i.p. administration, animals inspected at 7 to 44 days after initiation of injections, histopathology study revealed changes in liver, muscle, kidney and nerve tissue. Marked nerve degeneration was noted and synapses were most vulnerable.			

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there is a significant possibility that children are more sensitive to the toxic effects of lindane than adults. Although limited data are available at the present time to establish that children display an increased sensitivity to lindane, it is believed that pubescent children are likely to have a heightened susceptibility to harm from pesticide exposure in general. Some of the factors likely to make pubescent children more susceptible than adults to the toxic effects of pesticides include the "greater uptake of (pesticides) in the developing tissue and organ systems of younger aged children", "increased susceptibility to asthma", "increased susceptibility to agents that interfere with calcium metabolism", "increased susceptibility to agents that interfere with protein utilization", and "increased sensitivity to hormonal imbalances." (Memorandum from Peter F. Infante, Director, Office of Carcinogen Identification and Classification, OSHA, to Grover Wren, Director, Health Standards Program, OSHA (June 16, 1978), cited in *National Association of Farmworkers Organizations, et al. v. Ray Marshall*, U.S. Court of Appeals, D.C. Civil Action No. 79-1044). On the basis of similar developmental factors, prepubescent children would also be expected to display a greater sensitivity to pesticides. Moreover, the potentially higher exposure per unit of body weight for young children and the possibility of underdeveloped detoxification systems in very young children would also appear to pose significant concerns.

Furthermore, the Agency's concern about the susceptibility of children is supported by both animal data on the effects of lindane and clinical cases of lindane poisoning in children.

An experiment with rabbits showed that immature animals display a very pronounced sensitivity to lindane compared to adult animals. Hanig et al. (1976) treated rabbits with a single topical application of 1 percent lindane at 60 mg/kg. Young adult (2 to 3 kg) and just-weaned (6-week-old) male New Zealand rabbits were either shaved; shaved and depilated; or shaved, depilated, and "stripped" with adhesive tape. The animals were observed for three weeks. Fifty percent of the young adults that had been shaved, depilated, and stripped showed only mild excitement after treatment. Treated weanling groups, however, showed severe CNS symptoms of excitement, convulsions (all groups), and death (50 to 70 percent of the animals) if the skin was depilated and stripped. The Agency has reviewed this study and has concluded that the data presented support its concern that children may be more sensitive than adults to the acute toxic effects of lindane.[14]

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[14] The weanling controls which were shaved, depilated and stripped did not exhibit excitement or convulsions but did suffer a high mortality rate. The authors concluded that the stripping process was too severe for the weanling rabbits and that the high mortality rate of the controls did not negate the high incidence of excitement and convulsions in the treated group.

A number of clinical cases of lindane poisoning in children also heighten the Agency's concern about the special sensitivity of children to the acute effects of lindane. One case which illustrates the significance of lindane's potential to produce acute effects of the central nervous system involved the recent death of a two and one half month old infant who had been treated for scabies with a commercial lindane product. Lindane was found in the child's heart blood at 33 ppb, in the urine at 2 ppb, and in the brain tissue at 100 ppb. Doctors who reviewed the case at the University of Miami Epi-Studies Pesticides Laboratory agreed that the concentration of lindane in the brain at a level three times higher than in the blood was the most probable cause of death (University of Miami Memo, 1979).[15]

In view of the potential of heightened sensitivity of children to pesticide exposure, a cautious approach is warranted toward setting margins of safety levels for children exposed to lindane. Current scientific information is, in the Agency's judgment, insufficient to set separate margins of safety levels for children. The most that can be said is that the margin of safety figures for adults are probably too high to assure the safety of children.

a. Comments Submitted on Possible Adverse Effects: Population Reduction in Nontarget Avian Species

The Agency cited studies in the lindane RPAR notice which showed that exposure to DDT and its metabolite, DDE, caused eggshell thinning in wild birds. The Agency was concerned that lindane (an organochlorine pesticide like DDT) might adversely affect populations of nontarget avian species. In addition, a study on lindane's effects on chicken eggs was cited which showed that lindane reduced hatchability and reproductive efficiency. However, the Agency considered these data insufficient to initiate a rebuttable presumption.

No comments were submitted in rebuttal to this concern. The Environmental Defense Fund (30000/10:#43) suggested that exposure of lindane to avian species should be considered. The Agency has reviewed this concern (Memo, 1977) and has concluded that there is no new evidence showing adverse effects on avian species and that there is little evidential basis for concern. Because chickens are not representative of wild avians, no determination that lindane adversely affects nontarget avian species can be made on the basis of the chicken study cited in the RPAR notice.

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[15] Because it involves a child, the example of this infant death attributable to the CNS effects of lindane warrants comparison with the recent case of a 32-month-old Illinois boy who was diagnosed as suffering from aplastic anemia secondary to lindane exposure from a vaporizer used in his home. Refer to Subsection IV. A. 4.b above regarding blood dyscrasias as a possible adverse effect of exposure to lindane.

b. Comments Submitted and Additional Agency Findings on Isomerization

In Position Document 1 the Agency cited studies which suggested that lindane (gamma-BHC) may isomerize in the environment to alpha-BHC, and in rats to alpha- and beta-BHC. The question of isomerization was raised as a potential concern based on data establishing that the alpha and beta isomers of BHC induce statistically significant oncogenic changes in seven different rat and mouse strains. Three registrants, Hooker Chemical Co. (30000/10:#42), Franklin Laboratories (30000/10:#37), and Paper Products, Inc. (30000/10:#41) commented on the issue of isomerization.

The most extensive comments were submitted by Hooker Chemical Co. and these may be summarized as follows:

1) Chemical-driving forces favor degradation of lindane, not isomerization.

2) Isomerization of gamma-BHC to alpha-BHC apparently takes place in sediments, but to such a low extent that it is not of significance for the environment.

3) The fact that many research articles have reported degradation but not isomerization, and that the one article which did report isomerization of grass (Steinwandter, 1976a) used conditions in which substantial microbial populations were present, render it unlikely that isomerization takes place in plants to any considerable extent. The results of the Steinwandter study may also not be reproducible.

4) The Kamada (1971) rat study, cited in PD1, is deficient in several respects (enumerated below), and isomerization in rats is very doubtful.

a) The analysis of the rat tissues was carried out by gas chromatography using only one column.

b) There were only two animals in the control group.

c) In the livers of the control animals beta-BHC was found in rather high concentrations.

d) A comparison of the data from the rats treated with beta-BHC with the data from the control animals could be interpreted to indicate that beta-BHC is also isomerized to alpha-BHC.

e) No detailed information is given about the gas chromatographic determination of the purity of the isomers used. Although it is stated that in each active ingredient only one isomer was detectable, it is known that traces of other isomers are generally also present.

f) No details about the contamination of the feed and oil used are given. Oils in particular very often contain different amounts of organochlorine substances such as BHC isomers.

g) The appearance of the various isomers which were not administered in comparison to the values from the controls cannot be regarded as significant, and the appearance of these isomers as a result of isomerization is very doubtful.

Franklin Laboratories (30000/10:#37) and Paper Products, Inc. (30000/10:#41) pointed out additionally 1) that the formation of alpha-BHC from an intermediate benzene tetrachloride is difficult to visualize since two chlorines would have to be added back to the molecule in the process, and 2) that because of apparent contamination of the food fed to the rats, it is difficult to interpret Kamada's work.

The Agency's response to these collective comments is presented in Subsections 1) through 4) below. The discussion also includes other information received by the Agency since the publication of PD1.

1) Chemical Driving Forces

Although, as noted in PD1, the relative thermodynamic stabilities of the four major BHC isomers are in the order gamma<alpha<delta<beta, the chemical reactivity of the gamma isomer (lindane) clearly favors elimination pathways rather than isomerization pathways. Numerous reports in the scientific literature, published both before and since PD1 was issued in February 1977, have demonstrated the predominance of dechlorinated degradation products under widely varying conditions in soils and in mammals. Kinetic factors clearly control the chemical reactivity of lindane, and the relative thermodynamic stability of the isomers does not constitute evidence for actual environmental conversion of lindane to the other BHC isomers.

2) Isomerization in the Environment

Studies by Newland et al. (1969), Benezet and Matsumura (1973), and Matsumura et al. (1976) were cited in PD1, all of which reported the conversion of lindane to the alpha isomer. In the Newland study, lake sediment was added to dilute aqueous solutions of ^{14}C-labeled lindane, and either air or nitrogen gas was bubbled through the suspension to maintain aerobic or anaerobic conditions. After 2100 hours of incubation, the presence of alpha-BHC in the anaerobic suspension was established by gas chromatography on five different columns, by fortification with authentic alpha-BHC followed by gas chromatography, and by a combined TLC/GC technique. The yield of alpha-BHC was apparently in the range of 3 percent, and 83 percent of the radioactivity initially present in the system was lost by volatilization.

The studies by the Matsumura group also reported the formation of small amounts of alpha-BHC from the microbial degradation of lindane. In these studies Pseudomonas putida was cultured in the presence of ^{14}C-labeled lindane, together with various cofactors. When nicotine adenine dinucleotide (NAD) was present in the culture, 3 percent of alpha-BHC was reported as a metabolite after 20 days incubation. In this case 73.5 percent of the original radioactivity was recovered as lindane. Without NAD, or in the presence of many other cofactors, no alpha-BHC was reported. Very little degradation proceeded under these conditions.

Hooker's comment on these studies did not dispute the formation of the alpha-isomer, but instead concluded, based on the low yields of this isomer and much higher yields of other degradation products, that "the isomerization of gamma-BHC in the environment is not of significance for the environment."

A number of additional studies on the microbial degradation of lindane have been published since PD 1. A brief survey of the more important studies follows. Kohli et al. (1976) described several radio labeling studies of lindane degradation in hydroponic lettuce cultures. After four weeks under aerobic conditions, 78 percent of the total radioactivity was lost through evaporation, 17.3 percent was recovered as unchanged lindane, and the rest consisted of chlorobenzene metabolites, including hexachlorobenzene, and chlorinated phenols. These metabolites were identified by gas chromatographic and mass spectral comparison with authentic materials. No alpha-BHC was reported.

Tu (1976) reported the presence of a large number of lindane metabolites from several bacterial and fungal cultures. Chlorocyclohexenes and chlorobenzenes predominated, but quantitative results were not reported.

Heritage and MacRae (1977) reported the degradation of both lindane and alpha-BHC by Clostridium sphenoides under anaerobic conditions. In cell suspensions of this soil bacterium, the gamma- and alpha isomers typically disappeared after two and four hours, respectively. Tetrachlorocyclohexenes were identified as intermediates by gas chromatography and mass spectrography. Alpha-BHC formation from the lindane-inoculated culture was not reported.

Mathur and Saha (1977) studied the degradation of radiolabeled lindane by soil bacteria under both aerobic and anaerobic conditions. After eight weeks incubation, 70-86 percent of the ^{14}C-radioactivity was recovered as lindane from the anaerobic cultures. The principal metabolites were di- and tri-chlorobenzenes and tetra- and pentachlorocyclohexenes, and no alpha-BHC was reported.

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Kohnen et al. (1975) measured the release of chloride ion and carbon dioxide from ^{36}Cl- or ^{14}C-labeled lindane in submerged (anaerobic) and moist (aerobic) soil cultures. Under anaerobic conditions, 86.5 percent of total chlorine was liberated as chloride ion in 52 days, while only 6 percent of total carbon was liberated as $^{14}CO_2$ in 77 days. The amount of isomerization to alpha-BHC was stated to be 1.1 percent, but no experimental details were given. By comparison, under aerobic conditions only 9 percent of total chlorine and 3 percent of total carbon were liberated in 105 days.

In a later study by the same authors (Jagnow et al., 1977), a survey of bacterial cultures showed that 7-93 percent of total chlorine was released as chloride ion from lindane under anaerobic conditions. No data on the isomerization of lindane were presented. However, the following statement was made: "It cannot yet be decided, whether these HCH-isomers were formed by isomerization of gamma-HCH during incubation, or if they were already present in the gamma-HCH preparation and became relatively enriched during the degradation of the gamma-HCH."

Engst et al. (1979) studied the anaerobic degradation of lindane by a mixed culture of bacteria and reported the transitory appearance of alpha-BHC during 39 days of incubation. The highest ratio of alpha-BHC to lindane was 2.8 percent after about six days. Much lower levels of alpha-BHC, as well as even lower levels (not specified) of the delta- and beta-isomers, were indicated during later stages of the incubation. Pentachlorocyclohexene, tetrachlorobenzene, and unknown polar metabolites were also reported, but no yield data were given.

It seems reasonable to generalize from all of these studies on the microbial degradation of lindane that the major pathway of degradation involves dechlorination rather than isomerization. Metabolites of lindane containing fewer chlorine atoms are consistently reported. Moreover, the disappearance of lindane by volatilization, together with the appearance of chloride ion, strongly suggests that extensive degradation of lindane to lower molecular weight substances, including carbon dioxide, occurs in most cases. Several research groups have identified alpha-BHC and hexachlorobenzene as minor metabolites, but the extent of production of these metabolites appears to be no more than a few percent at best, and under most conditions they apparently are not detectable. Because the isomerization of lindane appears to require anaerobic conditions, which are generally sequestered from efficient exchange with the aerobic environment, and because alpha-BHC also appears to be degraded under anaerobic conditions, the comment by Hooker Chemical Co. that the microbial isomerization is not significant is accepted by the Agency.

3) Isomerization in Plants

A study by Steinwandter (1976a), in which isomerization of lindane to alpha-BHC in plants was reported, was cited by Hooker Chemical Co. during the rebuttal period though it was not mentioned by the Agency in PD1. In this study, lindane was converted to alpha-BHC after application to hay for six months. At the end of the experiment, the hay had decayed and was densely colonized by microbial growth. In comparison to the control sample, which had 0.018 ppm of alpha-BHC, the treated sample had 0.043 ppm of the alpha-isomer. Since the hay had been treated with 2.5 ppm of lindane, the formal yield of alpha-BHC was about 1 percent. In a communication to Hooker Chemical Co., Steinwandter (1976b) stated that he was unsure whether he could reproduce these results.

Since the publication of PD1, Steinwandter has published additional studies, in which the formation of beta-BHC from alpha-BHC at an apparent yield of about 2 percent was claimed (Steinwandter, 1978a), and which presented some crude rate data on the isomerization process (Steinwandter, 1978b). These reports have similar difficulties with contamination of experimental material and present only minimal additional evidence. The data (Steinwandter, 1978b) appear to show that alpha-BHC is formed rapidly but also is degraded rapidly. No data are presented concerning the fate of the approximately 98 percent of the lindane that did not isomerize to alpha-BHC. The resolution of peaks in the chromatograms presented is not adequate to allow unequivocal identification and quantification of alpha-BHC.

The validity of the conclusion that lindane is isomerized to alpha-BHC in plants is questionable because of the contamination of experimental materials by the BHC isomers, because of the presence of the dense microbial growth in the materials, and because of the lack of adequate analytical detail. Since the yields of alpha-BHC, beta-BHC, and HCB are at best low (1-2 percent), the Agency must conclude that isomerization of lindane to its isomers does not take place to any appreciable extent.

4) Isomerization in Rats

The Agency cited in PD1 a study by Kamada (1971) in which each of the four BHC isomers were fed for one week to separate groups of four rats each. Blood, urine, liver, and kidneys were then analyzed for each of the isomers. A fifth group of four rats was included as a control. Kamada reported levels of beta-BHC in the livers in excess of control levels when the rats were fed either alpha-BHC or gamma-BHC. He concluded that these isomers may be isomerized to beta-BHC by the rat.

A number of deficiencies in this study (listed earlier) have been pointed out by Hooker Chemical Co. These points are generally correct. In fact the rats in the control group had high levels of alpha-BHC (0.05 ppm), beta-BHC (.02 ppm), and gamma -BHC (0.15-0.16 ppm) in the liver, as well as extremely high levels of alpha-BHC and especially gamma-BHC (4.3 ppm) in the kidneys. Chadwick (1976) also pointed out some of the same deficiencies and argued that it is difficult to interpret the results of the study.

The Agency contacted Dr. Kamada in 1978 and obtained the following additional information (Kamada, 1978):

1) The BHC isomers used in the study had the following purity: alpha-BHC, 99 percent; beta-BHC, 99.7 percent; gamma-BHC, 99 percent; and delta-BHC, 99 percent. Peaks of other isomers were not observed on gas chromatograms.

2) The commercially sold feed fed to rats was contaminated with gamma- and alpha-BHC, as well as with much lower levels of beta-BHC. Exact records of this data are no longer available.

3) No attempt was made to measure other lindane metabolites in the rat tissues.

In an attempt to reproduce the results of Kamada, Eichler and Heupt (1977) fed lindane of 99.95 percent purity to 29 rats for eight weeks. They found 767 ppm of lindane in the kidneys but only 0.047 ppm of alpha-BHC, which is less than the amount of the alpha-isomer expected on the basis of the measured impurity. No alpha-BHC was found in the liver at a detection limit of 0.002 ppm. A research group at CIEL in Germany is presently carrying out additional studies on the possibility of lindane isomerization in rats. No data are as yet available to the Agency.

Copeland and Chadwick (1979) treated groups of weanling rats with several different levels of lindane over periods of time extending to 24 weeks, followed by a single large oral dose 24 hours before sacrifice. They reported that the levels of alpha-BHC in the livers did not exceed levels which would be expected on the basis of the alpha-BHC consumed as an impurity, and concluded that bioisomerization does not play a significant role in the metabolism of lindane by the rat.

Based on the totality of information available on the metabolism of lindane by rats (e.g. Engst et al., 1976), on the failure of other research groups to reproduce the results of the original Kamada study, and on the problems of contamination in that study, the Agency concludes that isomerization of lindane to its isomers in rats has not been established.

B. Exposure Analysis

1. Persistence and Exposure

A persistent pesticide provides a greater opportunity for exposure than a non-persistent pesticide. Since pesticidal risk is a function of exposure and toxicity, it follows, all else being equal, that a persistent pesticide presents a higher risk potential than a non-persistent pesticide. Lindane, as we show below, is a persistent pesticide.

As discussed in Position Document 1, lindane is a member of a class of organochlorine pesticides, which, as a rule, are more persistent in the environment than other classes of pesticide compounds. This persistence is due largely to the chemical stability of the organochlorine compounds and their slow degradation by plant and animal enzymatic systems. Lindane is quite mobile in the environment. Residues of lindane have been detected in all types of environmental media, including water, air and soil samples, homes, and plant and animal tissues. The presence of lindane residues at sites far removed from its application attests in particular to the long term persistence of the pesticide. Lindane residues have been found, for example, in rainwater samples from several countries (Ref. 8 & 9,PD #1), in birds, penguins, skuas and cormorants, fish, Nototheria sp. and planktonic krill in Antarctica (Tatton and Ruzicka, 1967), and in seals and an arctic fox in Greenland (Clauscen, et al., 1974). Lindane residues have been found at low levels in drinking water from various sources in the United States (EPA, 1976) and in ambient air samples from selected states. For example, during the years 1970 to 1972, lindane residues were found in 68% of 2,479 ambient air samples from 14 to 16 selected states; in 1976, lindane air levels of 2.2 ng/m^3 were detected in Miami, Florida; 0.3 ng/m^3 in Fort Collins, Colorado; 0.5 ng/m^3 in Lafayette, Indiana; 16.2 ng/m^3 in Jackson, Mississippi; and 0.4 ng/m^3 in Harrisburg, Pennsylvania (EPA, 1976b).

The persistence of lindane in the soil is dependent on a number of factors, including soil type, soil organic matter, water content, soil temperature, and lindane concentration. Although lindane is eliminated from the soil at a faster rate than most other chlorinated hydrocarbon insecticides, it is still persistent when compared with other classes of pesticides. In long-term tests of the persistence of lindane, for example, the remaining residues in soil after a 15-year period ranged from 0.2% to 3-8% of the amount of lindane applied (Lichtenstein et al., 1971 and Voerman and Besemer, 1970). Lindane residues in soil appear to be fairly low; for example, in 1970, 0.4% of 1506 cropland sites sampled had detectable lindane residues which varied between 0.01 and 0.15 ppm. The primary factor responsible for the low residue levels of lindane in the soil is the high vapor pressure of lindane which results in a rapid volatilization of the compound from the soil. This volatility lessens the availability of the compound for degradation by soil microbes, but ultimately contributes to the persistence of lindane in non-soil media.

Lindane has been found in the body, organs and tissues of mammalian, avian and aquatic species with greatest shortage in the body fat. Monitoring data show, for example, that lindane residues occurred in human adipose tissue in 0.77%, 1.56% and 0.56% of the samples collected during 1970, 1973 and 1974. The mean level of lindane residues in human adipose tissue for the years 1970 to 1974 was less than 0.1 ppm on a lipid basis (Kutz et al., 1976).

2. Comments Submitted on Exposure

a. Comments Submitted on Dietary Exposure

Hooker Chemicals (30000/10:#42) and Burroughs Wellcome Co. (30000/10:#4A) submitted a total of seven comments on dietary exposure of humans to lindane, which the Agency has evaluated (EPA 1978d).

Hooker Chemicals argued in general terms that residues of lindane in food are low. In addition, Hooker cited FDA data which showed that the daily intake of lindane has dropped from 0.007 mg/kg per day in 1967 to 0.0000084 mg/kg per day in 1974. Hooker also noted that, although no analytical method can distinguish between gamma isomer resulting from BHC or lindane use, the decline in lindane intake follows the decline in the amount of BHC produced and used in the U.S. over the years. Burroughs cited the same FDA data for 1973-1974 showing a range of lindane residues in beef from 0.0004 to 0.012 ppm.

The Agency agrees that lindane levels in food have decreased. The Agency believes, however, that if the FDA market survey errs, it is more likely to underestimate than overestimate residues actually ingested, because of FDA's method of compositing samples before chemical analysis. The FDA market basket survey remains the most reliable source of residue data available. Since BHC is no longer in general use, the Agency considers that source of gamma-BHC to be no longer pertinent.

Hooker submitted data as evidence that lindane residues on vegetables and fruit are generally lower than 0.5 ppm. The Agency agrees that residues of lindane on fruit and vegetables are generally less than 0.5 ppm.

Hooker Chemicals (30000/10:#42) cited a study showing that the application of lindane as a seed treatment did not result in detectable lindane levels in wheat, oats, and barley. The Agency notes that a review of FDA's monitoring data of whole grain for human consumption showed 2.5 percent samples positive for lindane at a mean residue level of <0.03 ppm (1978d).

b. Comments Submitted on Exposure Via Drinking Water

Hooker Chemicals (3000/10:#42) commented that lindane residues in drinking water are generally well below the limit of 0.004 ug lindane/liter set by EPA's Water Supply Division.

Table II-6. Average Lindane Residues in Food (by Composite Category)

Composite Food Category	FDA Food Factor	Avg of All Samples (ppm)	Daily Intake In mg/1.9 kg diet (70-kg adult)
Dairy Products	25.7%	0.0027	0.00135
Meat, Fish, & Poultry	9.0%	0.0017	0.00030
Grain and Cereals	14.2%	0.0001	0.00003
Potatoes	6.2%	Trace	0.00048
Leafy Vegetables	1.8%	0.0	0.0
Legume Vegetables	2.3%	0.0	0.0
Root Vegetables	1.1%	Trace	0.00009
Garden Fruits	3.1%	0.0015	0.00009
Fruits	7.4%	0.0	0.0
Oils, Fats & Shortening	2.4%	Trace	0.00018
Sugars and Adjuncts	2.8%	0.0029	0.00016
Beverages	24.0%	0.0	0.0
Total			0.00266

Most of the data cited by Hooker on this issue derived from Position Document 1. An additional study by Bevenue (1971) found only 4 percent of 45 samples taken in Hawaii positive for lindane in drinking water. (The average was 0.0002 ug/liter.) Another study, Achari (1975), found residues of 1.19 ppt in ground water (mostly wells) in South Carolina. Considering the information just cited and the low residues of lindane reported in surface waters, which are more likely to be contaminated with pesticides than is drinking water, the Agency finds it reasonable to agree with the registrant that lindane residues in drinking water are generally below 0.004 ug/liter (EPA 1978d).

c. General Comments Submitted on Exposure Via Air Intake

Based on data in Position Document 1 (EPA 1977a), Hooker Chemicals (30000/10:#42) argued that normal air intake will expose the general population to between 0.00017 and 0.0017 ug lindane/kg per day, or 1/1,000,000 to 1/10,000 of the World Health Organization/Food and Agricultural Association's (WHO/FAO) acceptable daily intake (ADI) of 0.0125 mg/kg per day. Hooker also argued that even the highest lindane levels in air are far from hazardous to humans, and that relatively high levels of alpha-BHC in ambient air samples could not be due to isomerization of lindane to alpha-BHC in sediments followed by volatilization.

The Agency has evaluated this comment (EPA 1978d). Whereas Hooker used a respiratory volume of 6 liters/min, the Agency believes a more reasonable breathing rate for light work is 28.6 liters/min. Based on exposure to a 60-kg adult, the Agency has established a daily exposure of 0.011 ug/kg per day, or about 1/1,000 of the ADI. The Agency also points out that the importance of lindane residues in air is their contribution to the total body burden of lindane. The general issue of isomerization is addressed in Subsection II.A.4e, wherein the Agency concludes that isomerization in the environment is not of major significance but does add to the overall risk presented by lindane.

d. General Comments Submitted on Exposure Via Accumulation in Human Adipose Tissue

Based on data in Position Document 1 (EPA 1977a), Hooker Chemicals (30000/10:#42) argued that lindane does not accumulate in human adipose tissue to hazardous levels. The registrant also argued that the only apparent reasons for beta-BHC in human adipose tissue are that large amounts of BHC have been used in the U.S. in the past 25 years, that residues of beta-BHC are still common in food, and that beta-BHC has a greater tendency to store in human adipose tissue and has a greater half-life in adipose tissue than other BHC isomers.

The Agency has reviewed these comments (EPA 1978d). According to data from EPA's Human Monitoring Programs for 1970 to 1974, 1.1 percent of samples analyzed showed lindane residues in human adipose tissue averaging 0.1 ppm. The Agency points out that the importance of these residues is their contribution to the total body burden of lindane.

Table II-7. Exposure Data: Summary of Application Practices Use-by-Use*

Use	Representative Formulation (EPA Reg. Numbers)	Recommended Rate of Application Used in Analysis - a.i. (% or ratio)	Mode of Application
Hardwood Logs and Lumber	1022-6, 148-106	1 pt (11% formulation) per 20 gal. water	Green chain dip vat Green chain spray lumber package dip vat
Seed Treatment	239-477	2 oz (23% formulation) per bu. at planting	Drill-box rig; hand-mixing with stick
Avocados	148-967	1 lb/acre 2x/year	Airblast sprayer
Ornamentals	904-185	0.5% w/v in water (1-15 times a year for commercial use) (once a year for homeowner use)	Commercial: Hydraulic sprayers Homeowners: 3-gallon compressed air sprayers
Cucurbits	239-229	0.033 to 1.0 lb/200 gal water/acre (as often as 3.3 times per season)	Boom (row drop) sprayer
Christmas Trees (Stump slash and trunk treatment)	8590-304 (358-97)	Stump slash 0.5% w/v in water to run-off point	Low pressure (back pack) sprayer
Foliar		0.06% w/v in water when needed	Hand gun pressure sprayer
Pecan Orchards	148-967	1 lb/acre Apply before pecan phylloxera galls are formed	Airblast sprayer
Forestry	904-185	1 gal. 0.5% per 50 sq. ft. of bark surface	Low volume spray (back pack) applied to run off point
Livestock	59-85	0.013% to 0.045% in water when needed	Medium pressure power sprayers
Structures	7234-52	0.5% w/v in water (no more than once a year)	Small areas:
Pineapples	8251-47 935-17	2-5 lb/acre (pre-planting)	Soil injection (8 to 18 inches under planting line)
Pets			
Pet collars	59-114	.32 g/collar (impregnated)	placed around animal's neck
Dog Wash	5620-5	8 oz. of 10% conc. mixed with 22.5 gal water	Dip
Dog Shampoo	257-125	0.5% w/v	Shampooed directly onto animal
Dog Dust	1222-57	1% dust	Hand-dusted
Household			
Shelf paper	3941-28	0.2% w/v impregnated in the paper	Shelves, cabinets, drawers of non-food areas, lavatories
Floor Wax	3696-32	0.5%	Hand, brush, or mop floor
Household spray	541-186	0.1% in petroleum distillates	Pressurized, electric, or hand sprayer
Fumigation Devices	1327-15, 16, 28	2.3% to 20%	Smoke, fume, or fog
Minor Uses			
Moth Spray - Industrial Use	4077-21	0.1% in petroleum solvents Apply at intervals no longer than 3 weeks	Propellant spray is directed to garments
Insect Spray - uninhabited buildings	962-376AA	20% w/v 1 part in 9 to 20 parts kerosene	Spray as aerosol or mist
Empty Storage Bin Fog Spray	2182-4	0.5 w/v in mixture with methoxych. [illegible] gal/250 ft^2 or 10,300 ft^2)	Fog or hand-spray

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Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Hardwood Logs and Lumber	**Dermal** a) Seven ml of aqueous solution wet 2 average hands up to the wrist. b) Total surface area of two hands = 0.082m^2. c) Total skin area exposed (head, neck, and hands) during operation = 0.294m^2. d) Operator is exposed to cumulative dose equivalent to single wetting of all exposed skin. e) Lindane concentration in final diluted mixture is 0.5% (from labels). **Respiratory** a) All surface areas surrounding dipping vat are saturated with lindane. b) Saturation vapor concentration of lindane 20°C = 0.5ug/l. c) Due to open air conditions, saturation equilibrium is not reached. d) 10% lindane saturation represents best estimate of air concentration. e) Adult male breathing rate = 1.8 m^3/hr.	16	0.09	2000	D: 32,000* R: 180*	2,400

Calculations:

Dermal: 7 ml or 7 g mixture x 0.5% x 0.294/0.082 = 0.125 g/day or 16 mg/hr.

Respiratory: 0.5 ug/l or 0.5 mg/m^3 x 0.1 x 1.8 m^3/hr = 0.09 mg/hr.

* D = Dermal
* R = Respiratory

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Seed treatment	**Dermal** Based on Hayes (1975): a) One gram of lindane 25% dust formulation can completely cover the hands ($0.082m^2$). b) Operator skin area exposed (head, neck, and hands) = $0.294m^2$. c) During mixing operation only 20% of lindane formulation reaches exposed skin.	180	4.5	1.7	D: 306* R: 7.7*	130,000
	Respiratory Based on US-HEW (1974): a) Average lindane formulation air concentrations surrounding drill-box rig = 10 mg/m^3. b) Adult male breathing rate = 1.8 m^3/hr. c) Operator spends approximately 60 minutes per day mixing seed.	**Calculations:** Dermal: 1 g x 25% x 0.294/0.082 x 20% = 180 mg/hr Respiratory: 10 mg/m^3 x 25% x 1.8 m^3/hr = 4.5 mg/hr				
Avocados	Based on Wolfe et al. (1967): a) Spraying operations for avocados are identical to those for other fruit orchards. b) Reasonable values for calculating dermal and respiratory exposures are 50 and 0.1 mg/hr, respectively (Wolfe et al., 1967). c) A single pest control operator treats one average avocado farm in one day, twice a year.	50	0.1	16	D: 800* R: 1.6*	

* D = Dermal

* R = Respiratory

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis: Estimation of Unit, Time & Exposure: Dermal mg/hr	Respiratory mg/hr	Exposure Duration hr/year	Annual Exposure mg/year	Cohort at Risk persons
Ornamentals Commercial Applicators	Based on Wolfe et al. (1974): a) Mean dermal and respiratory exposure levels are 3.6 and 0.021 mg/hr, respectively, as determined for fenthion spray solutions containing 0.06% a.i. and assumes 1 hr workday. b) A 0.5% w/w lindane solution is used. c) A commercial applicator works 3-8 hours a day for 1-15 days per year. d) A homeowner sprays only one hour per year.	30	0.2	3-120	D: 90-3600* R: 0.5-22*	30-1200
Homeowners				1	D: 30* R: 0.18*	75,000

Calculations:

Dermal: $3.6 \text{ mg/hr} \times \frac{0.5}{0.06} = 30 \text{ mg/hr}$

Respiratory: $0.021 \text{ mg/hr} \times \frac{0.5}{0.06} = 0.18 \text{ mg/hr}$

Use	Assumptions Used in Analysis	Dermal mg/hr	Respiratory mg/hr	Exposure Duration hr/year	Annual Exposure mg/year	Cohort at Risk persons
Cucurbits	Based on Staiff et al. (1975): a) Mean dermal and respiratory exposure levels are 0.4 and 0.001 mg/hr, respectively, as determined for paraquat solutions containing 0.025 w/w a.i. applied at 100 gal/acre. b) Spray-diluted lindane mixture contains 453 g of lindane in 200 gal water per acre (0.06% w/w).	1.9	0.005	2.45	D: 4.7 R: 0.01	950

Calculations:

Dermal: $0.4 \text{ mg/hr} \times \frac{0.06}{0.025} \times \frac{200}{100} = 1.9 \text{ mg/hr}$

Respiratory: $0.001 \text{ mg/hr} \times \frac{0.06}{0.025} \times \frac{200}{100} = 0.005 \text{ mg/hr}$

* D = Dermal
* R = Respiratory

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Christmas Trees (Stump-slash and trunk)	Based on Wolfe et al. (1974): a) Spray particle size distribution is similar to that involved in fenthion treatment using direct spray for mosquito control. b) Mean dermal and respiratory exposure levels are 3.6 and 0.021 mg/hr, respectively, as determined for fenthion spray solutions containing 0.06% a.i. c) There is a seasonal correction factor of 0.32 due to reduction of body surface area exposed during stump-slash treatment in early spring. d) Use dilution is 0.5% w/w for stump/slash and 0.05 for trunk.	9.6 (stump-slash) 3.0 (trunk)	0.2 (stump-slash) 0.02 (trunk)	9	D: 87 (stump)* R: 1.8 (stump)* D: 27 (trunk)* R: 0.2 (trunk)*	10,000**
		Calculations: Dermal: $3.6 \text{ mg/hr} \times \frac{0.5}{0.06} \times 0.32 = 9.6 \text{ mg/hr}$ (stump-slash) $3.6 \text{ mg/hr} \times \frac{0.05}{0.06} = 3.0 \text{ mg/hr}$ (trunk) Respiratory: $0.021 \text{ mg/hr} \times \frac{0.5}{0.06} = 0.2$				
(Foliar)	Based on Batchelor and Walker (1954): a) Spray particle size distribution is similar to that involved in hand-gun pressure spraying of fruit orchards with parathion. b) Mean dermal and respiratory levels are 56 and 0.2 mg/hr, respectively, as determined for parathion spray solutions containing 0.05% a.i. c) Use dilution of the lindane spray is 0.08% a.i.	90	0.3	9	D: 810* R: 2.7*	
		Calculations: Dermal: $56 \text{ mg/hr} \times \frac{0.08}{0.05} = 90 \text{ mg/hr}$ Respiratory: $0.2 \text{ mg/hr} \times \frac{0.08}{0.05} = 0.3 \text{ mg/hr}$				

* D = Dermal
* R = Respiratory
**Total estimated applicators, all application modes.

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis: Estimation of Unit, Time & Exposure: Dermal	Respiratory	Exposure Duration	Annual Exposure	Cohort at Risk
		mg/hr	mg/hr	hr/year	mg/year	persons
Pecan Orchards	Based on Wolfe et al. (1967): a) Spraying operations for pecan trees are identical to those for other fruit orchards. b) Reasonable values for calculating dermal and respiratory exposures are 50 and 0.1 mg/hr, respectively. c) A single pest control operator treats one average pecan farm in one day, once a year.	50	0.1	7.9	D: 395* R: 0.8*	1200

* D = Dermal
* R = Respiratory

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Forestry	Based on Wolfe et al. (1974): a) Mean dermal and respiratory exposure level of 3.6 and 0.021 mg/hr, respectively, as determined for fenthion spray solutions containing 0.06% a.i. b) Use dilution for lindane is 0.5% a.i. c) Applicators treat 32 trees per day, 5 minutes each tree, 30 days a year.	30	0.2	80.1	D: 2400* R: 16*	1000
		Calculations: Dermal: 3.6 mg/hr x $\frac{0.5}{0.06}$ = 30 mg/hr Respiratory: 0.021 x $\frac{0.5}{0.06}$ = 0.2 mg/hr				
Livestock	Based on Wolfe et al. (1974): a) Operator exposure in dipping operations is negligible compared with spray operations. b) Mean dermal and respiratory exposure levels are 3.6 and 0.021 mg/hr, respectively, as determined for fenthion spray solutions containing 0.06% a.i. c) Use dilution is 0.045% a.i. for lindane.	2.7	0.02	Beef 2.09 Pigs 2.39	D: 5.6* R: 0.04* D: 6.5* R: 0.04*	30,000 218,000
		Calculations: Dermal: 3.6 mg/hr x $\frac{.045}{.06}$ = 2.7 mg/hr Respiratory: 0.021 x $\frac{0.045}{0.06}$ = 0.016 mg/hr				

* D = Dermal
* R = Respiratory

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Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Structures Applicators	Based on Batchelor and Walker (1954): a) Dermal and respiratory exposures are 56 and 0.2 mg/hr, respectively, as determined for parathion spray solutions containing 0.05% a.i. b) Spraying time is one hour per home. c) A dilution of 0.5% lindane w/w is used. d) It is estimated that between 500-1,000 applicators treat 10,000 homes, that it takes one hour to treat one home, and that this is done 10-20 days per year.	560 Calculations: Dermal: $56 \text{ mg/hr} \times \frac{0.5}{0.05} = 560 \text{ mg/hr}$ Respiratory: $0.2 \text{ mg/hr} \times \frac{0.5}{0.05} = 2 \text{ mg/hr}$	2	10-20	D: 5600-11,200* R: 20-40*	500-1000
Residents	Based on USPHS Communicable Disease Center (1952): a) Dermal exposure is negligible. b) An 85-day weighted average concentration of lindane in the air of a treated room is estimated to be 0.05 ug/l. c) A dilution factor of 0.5 for diffusion into untreated second story living space. d) A 1.2 m^3/hr breathing rate. e) Occupants are exposed 24 hours per day for 84 days per year.	- Calculations: Respiratory: $0.05 \text{ ug/l} \times 0.5 \times 1.2 \text{ m}^3\text{/hr} \times 1000 \text{ l/m}^3 = 0.03 \text{ mg/hr}$	0.03	2016	R: 60*	10,000 (houses)

* D = Dermal
* R = Respiratory

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Pineapples	Based on Severn (1978): a) There is no dermal exposure. b) Low concentrations of pesticide vapors above soil surface are directly proportional to their vapor pressures. c) Inhalation exposure of pineapple workers to DBCP was estimated to be 13 ug/hr. d) Lindane vapor pressure = 3×10^{-5} mm Hg at 20°C; that of DBCP = 0.8 mm Hg at 21°C. e) A 14-hour work day, once a year, is assumed.	-	4.9×10^{-7}	14	6.9×10^{-6}	1600

Calculations:

Respiratory: $13 \text{ ug/hr} \times 3.0 \times 10^{-5}/.8 = 4.9 \times 10^{-7}$ mg/hr

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Pets Pet Collars	a) Lindane is released at a constant rate for 6-8 weeks. b) Lindane is incorporated into collar, not on surface; total dermal contact by human handling is negligible and unquantifiable. c) Data for 5% a.i. DDVP (Shell Chemical Company 1976) incorporated into cat collars can be extrapolated for lindane. The concentration of DDVP in the air of a room housing one animal wearing one 5% collar is 0.35 ug/m^3. d) There is no difference in the volatility of lindane and DDVP. e) There is a dilution factor of 10 to account for the difference between the study area (48 m^3) and a standard living area (480 m^3). f) Use formulation is 0.61% a.i. lindane. g) Sedentary breathing rate = 1.2 m^3/hr. h) A person would be exposed 24 hours per day,. 365 days per year.	-	5.1×10^{-6}	8760	R: 0.045*	ND**

Calculations:

Respiratory: $0.35\ \text{ug/m}^3 \times 0.61\%/5.0\% \times .1 \times 1.2\ \text{m}^3/\text{hr} = 0.0051\ \text{ug/hr} = 5.1 \times 10^{-6}\ \text{mg/hr}$

* R = Respiratory
** ND = Not Determined

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Dog Wash Veterinarians	a) A veterinarian exposes both hands to dilute product 5 min. day, 26 times a year. b) Final formula density = 0.85 g/ml at 10% w/w lindane, conc. = 0.085 g lindane/ml. c) 7 ml of solution can "just wet" hands. d) No respiratory exposure occurs.	0.14	-	2.17	D: 0.3*	130,000
		Calculations: Dermal: 8 oz x 29.57 ml/oz x 0.085 g/ml x 1/22.5 gal. x 1 gal./3785 ml x 7 ml x 1000 mg/g x 5 min./60 min. = 0.14 mg/hr.				
Owners (Post-treatment exposure)	a) No dermal exposure for owners occurs. b) Animal has access to area with volume of 12,000 ft^3. c) Use of lindane is 0.236 mg/ml of final solution for post wash exposure. d) After towel drying, 79 ml of wash solution is retained by small dog; 237 ml by large dog. e) When a dog is washed, there is exposure for 72 hours, once a year. f) Assumed dilution factor of 10 for air exchange. g) Assumed breathing rate = 1.2 m^3/hr.		8.9×10^{-5} (small dog)** 2.7×10^{-4} (large dog)**	72	D: 8.9×10^{-5}- 2.7×10^{-4}*	15,000,000
		Calculations: Respiratory (Post-Wash): 79 ml x 0.236 mg/ml x 1/12,000 ft^3 x 0.034316 ft^3/l x 1.2 m^3/hr x 0.1 = 1.3×10^{-4} mg/hr.				

* D = Dermal

* R = Respiratory

** Post-wash respiratory exposure

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Dog Shampoo Applicators	a) Concentrate comes in direct contact with shampooer's hands. b) Per washing, total volume of 15 ml soap comes in contact with hands. c) Contact time of concentrate with hand is 3 seconds, then 0.5% solution is diluted with water used to wet dog's hair (assumed to be 1/2 pint) and contact time with "diluted" soap is 5 min./dog wash. d) 7 ml "just wet" hands. e) There is no respiratory exposure during shampooing procedure. f) Lindane transfers to oily layer of dog's pelt.	23.8	-	2.2	D: 51.4*	ND**
		Calculations: Dermal: 0.5 g/100 ml x 15 ml x 10^3 mg/g x 1/265 ml x 7 ml x 60 min/5 min = 23.8 mg/hr				
Residents (Post-treatment exposure)	a) 15 ml (375 ug) of a 0.5% lindane formulation is retained by small dog; 45 ml (1115 ug) by large dog. b) Animal has access to area with volume of 12,000 ft^3. c) Assumed breathing rate = 1.2 m^3/hr. d) 7 ml "just wet" hands. e) Lindane volatizes for 72 hours after treatment; 26 treatments per year.		1.8×10^{-5} (small dog) 5.3×10^{-5} (large dog)	1872	R: 0.034-0.1*	
		Calculations: Respiratory (small dog): 375 ug/12,000 ft^3 x 0.034316 ft^3/l x 1.2 m^3/hr x 1000 l/m^3 x 1/72 x 1 mg/1000 ug = 1.8×10^{-5} mg/hr				

* D = Dermal
* R = Respiratory
**ND = Not Determined

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Dog Dust Applicators	a) Total lindane (1% dust) formulation contacting skin represents 20% of maximum amount that would cover exposed skin area intentionally dipped in lindane dust (1 g fine powder needed to completely cover 1 pair of hands, or 0.08 m^2). b) Maximum dust inhaled over 2 minute treatment period is 10 mg/m^3. c) All "dust" is respirable size (10 u or less). d) 0.294 m^2 is the area of exposed skin from neck, head, hands and forearms. Area of hands is 0.08 m^2. e) A treatment takes 2 minutes and is repeated every two weeks for the entire year, i.e. 26 treatments. f) Lindane will volatilize at a steady rate for 3 days, at which time all lindane will have vaporized.	220.5	0.12	0.87	D: 191* R: 0.1*	ND**
		Calculations: Dermal: 1 $g/0.08\ m^2 \times 0.294\ m^2 \times 0.01 \times 1000\ mg/g \times 0.2 \times 60\ min/2\ min = 220.5\ mg/hr$ Respiratory: $10\ mg/m^3 \times 1.2\ m^3/hr \times 0.01 = 0.12\ mg/hr$				
Residents (Post-treatment exposure)	a) The assumptions used for dog wash, resident respiratory exposure, apply to exposure to dog dust. b) A typical pet requires 2 oz (56 g) of 1% powder per treatment. c) There is no dermal exposure. d) A resident would be exposed 12 hours per day, for 3 days per treatment, 26 times a year.	-	0.0027	R: 2.53*		ND**
		Calculations: Respiratory: $56\ g \times 0.01 \times 10^3\ mg/g \times 1/72 \times 1/12{,}000\ ft^3 \times 0.034316\ ft^3/l \times 1.2\ m^3/hr \times 1000\ l/m^3 \times 0.1 = 0.0027\ mg/hr$				

* D = Dermal

* R = Respiratory

**ND = Not Determined

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Household Uses						
Shelf Paper	a) Inhalation is primary route of exposure. b) After 105 days, 40% of the lindane will have vaporized. c) A 12-foot roll of shelf paper containing 15 mg lindane per ft^2 of paper is used to treat three 4 X 4 X 8 meter rooms. d) Assume a 1.2 m^3/hr breathing rate. e) Assume no dermal exposure.	-	0.002	2520	R: 5*	11,000,000
		Calculations: Respiratory: 15 mg/ft^2 x 0.4 x 12 ft^2 x 1/384m^3 x 1/105 x 1.2 m^3/hr = 0.002 mg/hr				
Floor Wax	a) One pound of wax treats 800 ft^2 17 times per year. b) Lindane will dissipate from waxed surfaces totally over a 3 week period. c) The air exchange is assumed to be 0.33 per hour due to outside air infiltration in a 12,000 ft^3 house. d) Per treatment, 2770 mg lindane is applied, which is equal to 4.5 mg/hr evaporation rate. e) Assume no dermal exposure. f) Assume a 1.2 m^3/hr breathing rate.	-	0.01	8760	R: 88*	100,000,000
		Calculations: Respiratory: 4.5 mg/12,000 ft^3 x 0.66 x 0.034316 ft^3/1 x 1.2 m^3/hr x 1000 1/m^3 = 0.01 mg/hr				

* R = Respiratory

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Household Spray	a) A coarse spray (0.1% w/w lindane) has 0.01% particles between 40 and 60 microns, and 0.1% between 40 and 100 microns, with 95% of spray being deposited on surfaces. b) A 12,000 ft^3 house will have 12 oz applied over 5 minutes, once a year. c) Assume no dermal exposure. d) Assume a breathing rate of 1.2 m^3/hr.	-	0.0001	0.08	R: 1.0×10^{-5}*	ND**
		Calculations: Respiratory: 12 fl oz x 0.001 x 29.6 ml/fl oz x 0.001 x 1000 mg/ml x 1/12,000 ft^3 x 0.034316 ft^3/l x 1.2 m^3/hr x 1000 l/m^3 x 5 min/60 min = 0.0001 mg/hr				
Fumigation Devices	(Based on WARF Institute Inc., 1970: Average air concentration is 0.014 ug/l on a year round basis (26 applications per year).	-	0.017	8760	R: 149*	ND**
		Calculations: Respiratory: 0.014 ug/l x 1.2 m^3/hour x 1000 l/m^3 x 1 mg/1000 ug = 0.017 mg/hr				

* R = Respiratory
**ND = Not Determined

Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Minor Uses						
Moth Spray - Industrial Use a) Applicators	Based on Gay et al. (1975): a) Aerosol of 0.1% lindane produces 50% of particles 10 microns or less and 50% between 10 and 40 microns. b) Ninety percent of spray impinges on clothing and therefore is not subject to inhalation. c) Clothes are treated in well-ventilated areas for a 2 minute period at a time. d) Lindane concentrations in vicinity of spray and at time of spray are similar to those of a 30% Freon 12 formulation, which was 44.25 ppm in the breathing zone. e) All other components of the Freon 12 formulation behave in a similar manner, but their air concentrations are directly related to the concentration stated in the Freon 12 formulation. f) Spray repeated 26 times per year.	-	0.21	0.87	R: 0.18*	ND**
		Calculations: Respiratory: $44.25 \times 0.1/30 \times 0.00119$ mg/l x 1.2 m^3/hr x 1000 l/m^3 x $0.1 = 0.21$ mg/hr				
b) Occupants (Post-Treatment exposure to Impregnated Materials)	a) Twenty-eight grams of 0.1% spray are used every 2 weeks on a year-round basis. b) Vaporization rate is continuous over 2-week period, at which time all lindane vaporized. c) Effective volume of work space is 6000 ft^3 infiltration from outside is .33 times per hour. d) Exposure is 10 hrs per day, 365 days per year.	-	3.8×10^{-4}	3650	R: 1.4*	
		Calculations: Respiratory: 28g x 0.001×10^3 mg/g x 1/336 hr x 1/6000 ft^2 x 0.034316 ft^3/l x 1.2 m^3/hr x 1000 l/m^3 x .66 = 3.8×10^{-4} mg/hr				

* R = Respiratory

** ND = Not Determined

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Table II-8. Exposure Data: Summary of Exposure Analysis -- Use-by-Use (Cont.)

Use	Assumptions Used in Analysis	Exposure Analysis				
		Estimation of Unit, Time & Exposure				Cohort at Risk
		Dermal	Respiratory	Exposure Duration	Annual Exposure	
		mg/hr	mg/hr	hr/year	mg/year	persons
Minor Uses (Cont.)						
Insect Spray - Uninhabited Buildings	a) A concentrate of 20% lindane is diluted 1/9 (2.2%) and applied as an aerosol. b) Treatment time is 2 minutes with no secondary exposure 12 times a year. c) Air concentration assumed to be comparable as in Gay et al., 1975: 44.25 ppm after a 2 minute spraying with a 30% freon formulation. d) The breathing rate is assumed to be 1.2 m^3/hr. e) 1 ppm of lindane in air = 0.0119 mg/l.	-	46.7	.40	R = 18.7*	ND**
		Calculations: Respiratory: 2.2/30 x 44.25 ppm x 0.0119 mg/l/ppm x 1.2 m^3/hr x 1000 l/m^3 = 46.7 mg/hr				
Empty Storage Bin Fog Spray	a) All applications made with fogging machine. b) Droplets all 40u or less. c) Applicator exposed to residual airborn. particles, not to main fog cloud. d) Applicator does not wear respirator for average exposure of 5 min./appl. e) Formulation density = 0.8 g/ml. = 6.7 lbs/gal. f) Application 1 per mo., year round. g) A 0.5% w/w lindane solution is used. h) A dosage rate of a gallon per 10,000 ft^3. i) Particle size distribution of "fog" is in same order of magnitude as an aerially applied fine pesticide aerosol.	-	62.6	1	R = 62.6*	ND**
		Calculations: Respiratory: 1 gal/10,000 ft^3 x 0.034316 ft^3/l x 6.7 lb/gal x 454 g/lb x 0.5g/100g x 10^3 mg/ x 1.2 m^3/hr x 1000 l/m^3 = 62.6 mg/hr				

* R = Respiratory

** ND = Not Determined

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e. General Comments Submitted on Work-Place Exposure

Paper Products, Inc. (30000/10:#41A) submitted an epidemiological study on 64 employees whose work involved the use of lindane. Employees were divided into three groups according to years of exposure, and into another three groups according to blood levels of total BHC, including lindane. Eleven biochemical and eight hematological examinations were carried out. The study reported no differences between these groups of employees. The registrant argued that the study indicated no adverse effects from lindane on liver functions and hematopoietic systems of these workers.

The Agency does not disagree with the conclusions that no effects were noted. However, the limited population observed and extent of parameters measured dictate that the probability of noting an adverse effect would be negligible. Therefore, this study is decidedly not adequate to demonstrate that workers exposed to lindane experience no adverse effects to the liver or the hematopoietic system.

3. Dietary Exposure: Agency Determinations

For purposes of determining exposure to lindane from residues on food, the Agency has used data showing lindane residues calculated for 12 composite food categories from the FDA market basket (total diet) survey during the period 1971 to 1976 (EPA 1978e). Table II-6 shows the average lindane residue in each composite category, and the daily intake of lindane from this average in mg/1.94 kg diet. The total of the average daily exposure for all 12 food categories was then converted to mg/kg body weight per day for an average adult consuming 1.94 kg food/day.

The calculations shown in Table II-6 derive from actual residues and according to the Agency's best determination represent a reasonable estimate of dietary exposure. It should be pointed out, however, that average daily dietary exposure is likely to be somewhat higher for children than for adults. This would be due to 1) the relatively high residues of lindane in dairy products as compared to other food categories (Table II-6), and 2) the relatively high proportion of dairy products in the diets of young children.

4. Applicator and Homeowner/Householder/Occupant Exposure: Agency Determinations

The Agency has prepared estimates of dermal and respiratory exposure for those uses of lindane which are under review. Following the Agency's policy of making cautious and prudent assumptions in the face of

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the uncertainties which, given current methodologies, underlie exposure and risk calculations, these estimates are based on worst-case assumptions about actual use practices. Wherever possible, actual exposures are included in the calculations. Table II-7 shows representative formulations together with modes and recommended rates of applications. Agency calculations are based on representative formulations. Table II-8 is a summary of the Agency's exposure analysis of lindane, use by use; assumptions and calculations (60-kg adult weight assumption) are included. Assumptions are Agency-generated unless specifically designated otherwise. The following Subsections (a) through (n) briefly outline information pertinent to the assumptions proceeded upon for each use.

a. Applicator Exposure: Hardwood Logs and Lumber

The U.S. Department of Agriculture (30000/10:#49) submitted a description of three commonly used methods of BHC application in sawmills. Since lindane has replaced BHC in sawmills, the three methods now apply to lindane use: 1) Green chain dip vat, wherein freshly sawed boards are completely immersed prior to stacking; 2) green chain spray, wherein the lumber is conveyed through a spray booth equipped with a low-pressure spray system; and 3) lumber package dip vat, wherein stacked lumber is immersed into a dip vat, then allowed to drain. These procedures take place in a covered but open plant, with workers assisting in guiding, pulling, and stacking the lumber. The USDA states that workers who handle treated lumber are provided with rubber gloves, aprons or rain suits, and boots. If these items were used exactly as prescribed, little dermal exposure would result (EPA 1978d). However, subsequent inspection of some sites by EPA revealed that not all workers wore this protective gear, and not all gloves were impermeable to lindane. The Agency has calculated exposure for head, neck, and hands. It is assumed that the general surface areas surrounding the vats are saturated with lindane, and inhalation exposure results from vaporization peaking at a 10-percent lindane air concentration. Yearly exposure is assumed to be 8 hours per day, 250 days per year.

b. Applicator Exposure: Seed Treatment

This analysis is based on a typical formulation containing 25 percent lindane. The Agency has assumed that dermal and inhalation exposures from barrel treatment and seed drill-box rigs will be about equal. Exposure in these situations would be from air-borne dust generated during pouring of lindane powder and stirring of seed-powder mixtures, whether by hand or mechanically. The Agency has assumed also that seed treaters do not wear respirators or protective clothing, and that no more than 1.7 hours per day is spent at this operation.

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c. Applicator Exposure: Avocados

A lindane concentrate is diluted to a 0.04 percent weight-to-water (w/w) solution and applied as a spray to control infestation of avocado trees in Florida. Two applications are made at a 6-week interval. The Agency assumes that a single applicator treats one grove in a day, twice per year. Both dermal and respiratory exposures are anticipated.

d. Applicator and Homeowner Exposure: Ornamentals

Lindane sprays are used by homeowners and commercial nursery workers, usually as a dilution (0.5 percent w/w lindane in solvent) of a 20-percent lindane formulation. Hand-held hydraulic or compressed-air sprayersare used. Use patterns vary greatly and the range of possible exposures varies with duration of spraying time and with the number of applications per season. It is assumed that the applicator wears no protective clothing, gloves, or respirator (worst-case scenario).

Concerning homeowners, it was assumed that a homeowner expends one hour applying one pound of the formulation per year.

For commercial application it is assumed that 3600 acres are treated by a manpower force ranging from 30 to 1200 persons per year. Exposure time ranges from 3 to 120 hours per year per person. The extremes of this range are thought to be unlikely, but an average exposure time is not known.

e. Applicator Exposure: Cucurbits

For this analysis, the Agency has selected a typical formulation which contains 25 percent lindane diluted to a 0.06 w/w (lindane to water) spray, applied by a row crop boom sprayer. Three to four applications are made per season, and an applicator is thought to be exposed for 0.7 hours per application.

f. Applicator Exposure: Christmas Trees

Back-pack sprayers or handgun pressure sprayers are used to apply lindane solutions (0.05 percent to 0.5 percent w/w lindane in water) to Christmas trees and freshly cut stumps during winter, early spring, or summer for several pest control measures. Several application methods are used, with foliar treatments resulting in higher exposure than stump or trunk treatments. No exact numbers of applicators or applications for each use can be calculated because the pests and usage situations vary greatly. There are approximately 10,000 private Christmas tree growers throughout the United States, and the exposures per grower will be considered averages of total lindane usage. Since use practices and ambient temperature during treatment will vary greatly, the Agency has calculated an exposure range derived from a combination of the three main modes of

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use. The exposure and risk are expressed as a range between the extremes predicted for these uses. This should include most patterns of use and variations.

g. Applicator Exposure: Pecan Orchards

Lindane is used in a single-spray application to foliage with a ground airblast sprayer. A typical formulation of 12.5 percent lindane is diluted to a 0.05 percent w/w lindane in water spray. A single pest-control worker can treat one average farm in one day (approximately 8 hours), once per year. There are approximately 1200 pecan farmers in the United States, and we assume all use this procedure and each does his own spray operation. It is assumed that no protective clothing, gloves, or respirator are used.

h. Applicator Exposure: Forestry

Lindane is used in emergency conditions to spot-treat insect infestation sites. Large areas are not ordinarily covered by any single application, and the total use of lindane for controlling forest insect pests is about 4,000 pounds a.i. per year. A 0.5 percent (w/w of emulsified lindane in water) solution, diluted from a 20 percent formulation, is applied to the back of infested trees as a low-volume spray (back pack) to the point of run-off. The exposure analysis and risk calculations assume that no protective clothing, gloves,or respirator are used. However the Agency is aware that the U.S. Forest Service enforces its requirements for protective garb and safe-handling procedures. Use practices by applicators not employed by the Forest Service are less predictable. It is estimated that one operator could work at this operation for 30 days per year.

i. Applicator Exposure: Livestock

As an emulsion, lindane is applied as a pressurized spray or dip to farm animals. Treatment periods vary with labels, but treatments can be repeated as frequently as every two weeks. Considering geography and climate, range of pest to be controlled, etc., it is reasonable to conclude that no more than nine such applications would be done per annum. The emulsions are 2 percent and 25 percent concentrates diluted in water for the dip or spray. For purposes of this analysis, the Agency has selected a formulation which yields a final spray solution of 0.045 percent w/wlindane in water [EPA 1978e]. It is assumed that the operator wears no protective clothing, gloves, or respirator. Exposure estimates herein were calculated for spray application to swine, where exposure rates are highest. Exposure to dip vat operators is considered to be less than this due to the different operation procedure. In many cases, a lindane-toxaphene mixture is used for these applications, in which case the lindane exposure would be one half to one third that calculated here.

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The assumptions in this use profile represent a worst-case estimate for body surface exposed, concentrations used, and exposures per annum. An applicator is assumed to be exposed for about 2 hours per year in the actual spraying procedure.

j. Applicator and Occupant Exposure: Structures

A lindane emulsifiable concentrate (0.5 percent w/w lindane in water) diluted from a 20-percent lindane formulation is applied with a paint brush along small areas or applied with a coarse spray for large areas. An estimated 10,000 houses are treated per year.

For the applicator, both dermal and inhalation exposure are assumed to be relevant during the 1-hour application time. It is assumed that an average pest control operator treats between 10 and 20 homes per year.For home occupants, only inhalation exposure is anticipated.

Terminix International (30000/10:#26) argued that exposure to humans and non-target organisms is almost non-existent since lindane is retained in the wood under-structure where it is applied. The registrant also stated, "Because lindane is water based this also reduces its vaporization and dispersal into non-target areas." The Agency believes that lindane is more volatile than the registrant suggests. Lindane's vapor pressure at 30° C is 1.3×10^{-4} mmHg, compared to DDT at 7.3×10^{-7} and dieldrin at 9.9×10^{-6} (EPA 1978d). Data supplied by the CDC report are considered more definitive than the assumptions suggested by this registrant.

k. Applicator Exposure: Pineapples

Registration for use of lindane on pineapples is presently restricted to the state of Hawaii (EPA 1978e). In this use, lindane is injected into the soil with a fumigant before planting. Based on an exposure analysis for a similar use of DBCP, the Agency assumes that the primary route of exposure is by inhalation, and that at the low concentrations of pesticide applied, vapor concentration levels in air above soil will be a direct function of the vapor pressure, regardless of the relative mole fraction of the pesticide applied to the soil. After the lindane is injected, the field is covered with a plastic mulch. Potential for exposure depends on duties performed (equipment operator, mulch operator, or supervisor) during an assumed 14-hour working day. However, the anticipated hourly exposure associated with any of these functions is very small (approximately 5×10^{-7} mg/hr).

l. Applicator and Householder Exposure: Pets

(1) Pet Anti-Flea Collars

For this analysis, the Agency has selected a typical formulation containing 0.61 percent lindane and assumed a dilution factor of 10 (EPA 1978e). The Agency has extrapolated from Shell Chemical

Company (1976) data on 5 percent DDVP incorporated into cat collars. According to label directions, collars are effective for 6-8 weeks. A constant release rate during this period is assumed in connection with inhalation exposure. Because the lindane is incorporated into the collar rather than on the surface, dermal exposure via handling the collar is considered negligible.

(2) Dog Wash (Veterinary Use)

For this analysis, the Agency has selected a typical formulation containing 10 percent lindane (final use concentration is 0.085 gm lindane/ml) (EPA 1978e). The Agency assumes that a veterinary technician would treat 10 dogs per day, exposing both hands (unprotected) for 5 minutes during each dipping application. Inhalation exposure during this treatment period was not considered to be significant.

The Agency also considered post-treatment inhalation exposure to dog owners from lindane volatilized from the treated animals. The Agency assumed that the estimated residue would volatilize completely within three days, during which time the dog would be in common residence with the owner (EPA, 1978e). It is conceivable that some lindane may contact human skin if the animal is handled. This would be a highly variable and extremely small exposure. Absorption rates from brief contact would also be extremely small. However, even minimal exposure to and absorption by children must be viewed with extreme caution. The Agency has no data by which to gauge acceptable margins of safety for children.

(3) Dog Shampoo

For this analysis, the Agency has selected a typical formulation containing 0.5 percent w/w lindane in an oil soap base (EPA 1978e). The Agency assumes that the concentrated product will directly contact the shampooer's hands for 3 seconds, that a total of 15 ml soap will contact the hands during each washing, that the 0.5 percent concentrate will be diluted with one-half pint water, and that hands are in this diluted soap for 5 minutes during each washing. This procedure is repeated 26 times per year.

The Agency also examined post-treatment inhalation exposure to dog owners from lindane volatilized from dogs washed with the above formulation.

(4) Dog Dust

Animals are dusted with a one-percent lindane dust by hand application. The Agency assumes that 26 applications are made per year and residents are exposed to the animal 50 percent of the day post-application. Dermal exposure estimates were made for the treatment periods and inhalation exposure estimates were made for the immediate post-application period when lindane would volatilize from the animal's pelt (EPA 1978e).

m. Applicator Exposure: Household Uses

(1) Shelf Paper

Lindane-impregnated shelf paper is registered for use in non-food areas such as chests, drawers, closets, and storage areas. It is estimated that four and one-half million rolls of shelf paper are sold per year. The Agency assumes two rolls per year are used per household, and therefore that two and one-quarter million households per annum contain the product.

The human contact time, during which the paper is spread onto the desired area is very brief, and the Agency does not consider this dermal exposure significant. The primary route of exposure is inhalation of the vaporized lindane. The Agency assumes that 40 percent of the lindane will be released over a 105-day period at a constant rate.

Three registrants, Millen Industries (30000/10:#7A), Paper Products (30000/10:#41), and Athena Corporation (30000/10:#18A), submitted a total of five comments on exposure from lindane-treated shel paper (EPA 1978d). The comments dealt in general with exposure through food stored on treated shelf paper, and with lindane air concentrations from shelf paper in enclosed areas. None of these comments were pertinent to the Agency exposure analysis, which determined that the primary route of exposure from this product would be from inhalation of vapors in open areas (EPA 1978e.)

(2) Floor Wax

A solvent-based floor wax, laced with lindane (0.5 percent w/w) is used on various floor coverings at normal maintenance intervals (2-3 weeks). Application methods vary considerably.

Dermal exposure from application is anticipated but could not be estimated due to variation in application methods. Dermal exposure after application is also possible, especially for children. However, this highly variable situation also disallows a reasonable estimate of exposure.

The Agency assumes that the significant exposure mode will be due to respiration of the lindane vapors for three weeks after wax is applied to the floor.

(3) General Purpose Household Spray

A 0.1-percent lindane spray, formulated in petroleum distillate is registered for use in homes in surfaces of beds, carpets, draperies, etc. The spray produces particles about 40 microns size and 95 percent of the spray volume deposits on surfaces (EPA 1978e).

Contact with the sprayed surface could possibly result in some dermal exposure, but because of the varied nature and extremely varied surface areas (and types of surfaces) involved, calculation of dermal exposure is not possible. However, for most situations, dermal contact is likely to be insignificant (e.g. curtains, carpets, etc.). In some cases, the dermal contact may be relevant (crib mattresses, rugs in homes of small children), but defensible estimates cannot be made. The Agency assumes that 12 ounces of spray will be applied in a home (volume of 12,000ft^3) and the airborne particles will be evenly distributed throughout the home, and will have an effective longevity of 5 minutes.

(4) Smoke-fumigation Devices

These devices, variously termed fumigators, smoke generators, "bug-tabs," "moth-clouds," etc. produce over a very short time period either a smoke, fume, or fog of lindane with or without associated non-volatile particulates such as carbon. The purpose of the device is to produce a super-saturated suspension and/or vapor of lindane in an enclosed space.

Typical formulations for this use contain 2.3 percent to 20 percent lindane, and maximum vapor concentration varies from 0.4 to 1.9 mg/ft^3 (average of 0.8 mg/ft^3) [EPA 1978e]. The Agency assumes that treatments will be biweekly all year.

Grain storage bins, greenhouse, household areas, etc. are treated. Label directions instruct to clear the area of household pets and persons. Since it is assumed that persons are not in the area during fumigation, dermal exposure should not occur. Estimates of exposure due to contact of materials after application cannot be made, although such exposure may occur.

The Agency assumes that the major exposure mode would be via respiration of residual vapor in the household environment during the 2-week post-application period. It is important to note that lindane is absorbed onto the surface of many materials during vaporizer use. Exposure is therefore continuous as lindane is revolatized from these surfaces. A study by the U.S. Public Health Service demonstrated that 20% of the lindane residues initially deposited on painted walls during vaporizer use were present in these surfaces after 179 days (EPA, 1978e).

Continental Chemiste Corporation (30000/10:#19) submitted data by WARF (1970) to determine the amount of lindane deposited on food left exposed during smoke-fumigation. (Leaving food and eating utensils exposed during use is against label directions.) The Agency points out that the principal route of exposure to lindane from this product is through inhalation. Nevertheless, using the registrant's figures, the Agency has determined that a 60-kg person who eats from a 10-inch dinner plate the day after treatment with the registrant's product could be exposed to 0.1153 mg lindane, or 15 percent of the acceptable daily intake (Memo 1978c)

n. Applicator Exposure: Minor Uses

(1) Moth Spray (Aerosol) - Industrial Use

For this analysis, the Agency has selected a typical formulation containing 0.1 percent lindane in petroleum solvents and aerosol propellant (EPA 1978e). Spraying is biweekly, 26 times a year. The Agency assumes that 90 percent of the spray impinges on clothing and is not subject to inhalation; the remaining 10 percent will all be respirable. Treatment periods last for two minutes. The Agency also assumes that air concentrations will be similar to those cited in Gay et al. (1975). It is assumed that no significant amount of lindane impinges on the body surface during this procedure. There will also be inhalation exposure from revaporization from the treated surfaces if employees work near the stored materials.

(2) Insect Spray - Uninhabited Buildings

Lindane products are registered for use in buildings not occupied by humans or domestic animals where no feeds or foodstuffs are exposed. The compound is applied as an aerosol with kerosene or as a mist. Therefore, the pest control operator is assumed to be the only person at risk once per month, 12 months per year, for two minutes per application. (The total number of professional applicators exposed could not be determined.)

Because of the method of application, and nature of the area sprayed, inhalation exposure is considered to be the only significant route of exposure. To simulate a worst-case situation, use of the spray as an aerosol rather than a mist is represented in the exposure estimates. It is assumed that the applicator does not use a respirator.

(3) Empty Storage Bin Fog Spray

A lindane-methoxychlor mixture dissolved in aromatic petroleum distillates and methylene chloride is used for control of pests infesting empty bins, tanks, warehouse surfaces, basements, tunnelways, pits, etc. The 0.5 percent w/w lindane preparation is applied as a fog or hand spray to surfaces to the point of run-off.

The Agency assumes label restrictions and directions are followed, and thus an applicator will be exposed to the respirable residual airborne particles, but not enter directly into the main fogging cloud. Dermal dose is estimated to be insignificant. The Agency also assumes that applicators do not wear respirators.

4. Total Body Dose Calculations

Total estimated applicator exposure, both dermal and respiratory, for each use of lindane is given in Table II-9. In order to predict the total body dose anticipated from any individual scenario of exposure to lindane, the Agency has determined that the probable rate of dermal

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Table II-9. Estimated Applicator Exposure, Present Use Practices

Use	Dermal (mg/hr)	Respiratory (mg/hr)	Hr/day	mg/day* Dermal	mg/day* Respiratory	day/yr	mg/yr* Dermal	mg/yr* Respiratory
Hardwood Lumber	16	0.09	8	127.8	0.72	250	31,950	180
Seed Treatment	100	4.5	1.7	306	7.8	1	306	7.8
Avocados	50	0.1	8	402	0.6	2	804	1.2
Ornamentals								
Homeowners	30	0.10	1	30	0.10	1	30	0.10
Commercial	30	0.18	3-8	90-240	0.54-1.44	1-15	90-3,600	0.54-21.6
Cucurbits	1.9	0.005	0.7	0.12	0.0036	3.5	0.42	0.0126
Christmas trees	3-90	0.02-0.3	8	24-840	0.18-30	1.2	28.8-1,008	0.216-36
Pecan Orchards	50	0.1	7.9	396	0.6	1	396	0.6
Forestry	30	0.2	2.67	7.8	0.6	30	234	18
Livestock	2.7	0.02	2.1-2.4	5.4-6.6	0.06	1	5.4-6.6	0.06
Structures								
Applicators	560	2	1	55.8	1.8	10-20	558-1,116	18-36
Occupants	-	0.03	24	-	0.72	84	-	60.48
Pineapples	-	4.9×10^{-7}	14	-	6.6×10^{-6}	1	-	6.6×10^{-6}
Pet Uses								
Pet Collars	-	5.1×10^{-6}	24	-	1.2×10^{-2}	365	-	4.38
Dog Wash								
Applicators	0.14	-	0.083	1.2×10^{-3}	-	26	0.0312	-
Post-Application	-	9.0×10^{-5} - 2.7×10^{-4}	24	-	2.16×10^{-3} - 6.6×10^{-3}	3	-	6.48×10^{-3} - 1.98×10^{-2}

*Both dermal and respiratory

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Table II-9. Estimated Applicator Exposure, Present Use Practices* (Cont.)

Use	Dermal (mg/hr)	Respiratory (mg/hr)*	Hr/day	mg/day*		day/yr	mg/yr*	
				Dermal	Respiratory		Dermal	Respiratory
Dog Shampoo								
Applicators	23.8	-	0.083	1.98	-	26	51.48	-
Post-Application	-	1.8×10^{-5} - 5.3×10^{-5}	24	-	4.32×10^{-4} - 1.27×10^{-3}	78	-	3.37×10^{-2} - 9.92×10^{-2}
Dog Dust								
Applicators	220.5	0.12	0.03	6.6	3.6×10^{-3}	27	178.2	9.72×10^{-2}
Post-Application	-	0.0027	12	-	3.24×10^{-2}	78	-	2.53
Household Uses								
Shelf paper	-	0.002	24	-	4.8×10^{-2}	105	-	5.04
Floor Wax	-	0.01	24	-	0.24	365	-	87.6
Household Spray	-	0.0001	0.08	-	7.0×10^{-6}	1	-	5.8×10^{-6}
Fumigation Devices	-	0.017	24	-	0.408	365	-	148.92
Minor Uses								
Moth Spray, Industrial Use								
Spray	-	0.21	0.03	-	0.066	26	-	1.716
Impregnated Materials	-	3.6×10^{-4}	10	-	3.6×10^{-3}	365	-	1.314
Insect Spray, Uninhabited Buildings.	-	46.7	0.03	-	1.38	12	-	16.56
Empty Storage Bin Fog Spray	-	62.6	0.08	-	4.98	12	-	59.76

* Both dermal and respiratory

Table II-10. Total Body Doses (Applicators), Present Use Practices

Use	Dermal Uptake	Dermal mg/kg/day	Respiratory mg/kg/day*	Total mg/kg/day	Annual Total mg/kg/yr
Hardwood	10%	0.213	0.012	0.225	56.3
Seed Treatment	1%	0.051	0.130	0.181	0.181
Avocados	10%	0.67	0.01	0.68	1.35
Ornamentals					
Homeowners	10%	0.05	0.003	0.053	0.053
Commercial	10%	0.15-0.4	0.009-0.24	0.159-0.424	0.159-0.424
Cucurbits	10%	0.0022	6×10^{-5}	0.00226	0.000
Christmas trees	10%	0.04-1.2	0.027-0.04	0.067-1.24	0.00-1.5
Pecan Orchards	10%	0.67	0.01	0.68	0.60
Forestry	10%	0.13	0.01	0.14	4.2
Livestock					
beef	10%	0.009	1×10^{-3}	0.01	0.01
pigs	10%	0.011	1×10^{-3}	0.012	0.012
Structures					
Applicators	10%	0.93	0.03	0.96	9.6-19.2
Occupants	-	-	0.012	0.012	1.000
Pineapples	-	-	1.1×10^{-7}	1.1×10^{-7}	1.1×10^{-7}
Pets					
Pet Collars	-	-	1.0×10^{-6}	1.0×10^{-6}	6.6×10^{-4}
Dog Wash					
Applicators	10%	2×10^{-5}	-	2×10^{-5}	5×10^{-4}
Post-Application	-	-	3.6×10^{-5} - $1. \times 10^{-4}$	3.6×10^{-5} - 1.1×10^{-4}	2.0×10^{-3} - 0.4×10^{-3}

* 100% respiratory uptake assumed

Table II-10. Total Body Doses (Applicators), Present Use Practices (Cont.)

Use	Dermal Uptake%	Dermal mg/kg/day	Respiratory mg/kg/day*	Total mg/kg/day	Annual Total mg/kg/yr
Dog Shampoo			1 × 10^{-5} - 2.1 × 10^{-5}	0.003	0.078
Applicators	10%	0.003	7.2 × 10^{-6} -	7.2 × 10^{-6} -	5.6 × 10^{-4} -
Post-Application	-	-	2.1 × 10^{-5}	2.1 × 10^{-5}	1.6 × 10^{-3}
Dog Dust					
Applicators	1%	0.00123	6.7 × 10^{-6}	0.00123	0.032
Post-Application	-	-	5.4 × 10^{-4}	5.4 × 10^{-4}	0.042
Household Uses					
Shelfpaper	-	-	8 × 10^{-4}	8 × 10^{-4}	0.004
Floor Wax	-	-	4 × 10^{-7}	4 × 10^{-3}	1.46
Household Spray	-	-	1.3 × 10^{-7}	1.3 × 10^{-7}	1.3 × 10^{-7}
Fumigation Devices	-	-	6.8 × 10^{-3}	6.8 × 10^{-3}	2.5
Minor Uses					
Moth spray, Industrial Use					
Spray	-	-	1.1 × 10^{-4}	1.1 × 10^{-4}	2.7 × 10^{-3}
Impregnated Materials	-	-	6 × 10^{-5}	6 × 10^{-5}	2.3 × 10^{-2}
Insect Spray, Uninhabited Buildings	-	-	0.037	0.037	0.4
Empty Storage Bin Fog Spray	-	-	0.128	0.128	1.5

*100% Respiratory uptake assumed

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absorption of lindane from liquid formulations is ten percent, and one percent from dry formulations (Gross, 1978). Total body dose calculations for each use of lindane under review are summarized in Table II-10. In lieu of any information on oral or inhalation absorption, the Agency will assume 100 percent uptake of ingested or inhaled lindane (Gross, 1978).

C. Risk Assessment

Based on the exposure levels calculated for each use of lindane under review (Subsection II.B), the Agency has evaluated the degree of risk for carcinogenicity, fetotoxic effects, and acute and subacute central nervous system effects (EPA 1978g).

Because the Agency did not perform a quantitative exposure analysis for all the numerous minor uses of lindane, no quantitative risk assessment could be performed for minor uses other than those which are specifically under review. The Agency believes, however, thatsince there will be some level of exposure, however small, from these various uses, there will also be some corresponding risk to the users of these products. In addition, the Agency points out that, even though exposure to, and risk from, these minor uses may be small, their importance is in their contribution to the total body burden of lindane in the general population.

The succeeding subsections address the Agency's risk assessment of lindane in terms of 1) carcinogenicity, 2) fetotoxic effects, and 3) acute and subacute central nervous system effects.

1. Risk: Carcinogenicity

The Agency has extrapolated estimates of the carcinogenic risk from lindane exposure using the one-hit or exponential model with no assumed threshold.[16/] This model is used by the Agency in various forms for nearly all of its carcinogenic risk assessments. Admittedly, these risk extrapolations involve many uncertainties. Among those extrapolations which most subject the estimates to error are the high-dose animal to low-dose human conversions. Others are dose rate effect and the actual human exposure.

The following statement, published by the Interagency Regulatory Liaison Group (IRLG), is representative of the Agency's stance in the face of the uncertainties involved in quantitative cancer risk assessments:

> Despite the uncertainties, risk estimates can be and are being made, not only by some regulatory agencies but by other scientific bodies. Because of the uncertainties, however, and because

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[16/] Another estimate of risk was also developed, but this one used the log-probit model. The estimates from this model are being reviewed by the Agency's CAG and will be discussed in PD 4.

> of the serious public health consequences if the estimated risk were understated, it has become common practice to make cautious and prudent assumptions wherever they are needed to conduct a risk assessment. This approach has a precedent in other areas because of gaps in knowledge. Thus current methodologies, which permit only crude estimates of human risk, are designed to avoid understatement of the risk. It must be recognized, however, that in some circumstances this cannot be guaranteed because of other factors that may enhance human response, such as synergistic effects. Thus risk assessments should be used with caution in the regulatory process.
>
> With the present state of knowledge, the quantitative assessment of cancer risks provides only a rough estimate of the magnitude of the cancer risks; this estimate may be useful in setting priorities for control of carcinogens and in obtaining a very rough idea of the magnitude of the public health problem posed by a given carcinogen.[17/]

Multi-test evidence indicates that lindane causes oncogenic effects in mice. (Refer to Subsection II. A.I.) For purposes of extrapolating use-by-use estimates of the cancer risk posed by lindane to humans, the Agency has chosen to use the results of Thorpe and Walker (1973). This study was selected because the number of animals with tumors in both males and females was significantly above the respective controls, because the number of animals with tumors were comparable in each sex, and because the experiment had an extremely low P (pool) value ($<10^{-9}$). The Agency has little doubt that lindane is carcinogenic to mice at the doses used in this experiment (EPA, 1979).

Estimated cancer risks for each use of lindane under review are given in Table II-11. Dietary cancer risks are estimated at 1.7×10^{-5} or roughly 17 tumors per million people. The dietary risk is additive to other risks (e.g., applicator, residential) posed from exposure to lindane from other sources.

2. Risk: Fetotoxic Effects

The Agency's risk assessment of the reproductive and fetotoxic effects of lindane has necessarily focused on fetotoxic effects. The Agency was unable to perform a quantitative risk assessment of the general reproductive effects of the pesticide based on available data. Fetotoxic risk to humans has been evaluated by comparing the no observable effect level (NOEL) in animal studies with the highest estimated daily acute exposure for each use. The resulting ratios are referred to as margins of safety (MOS) and represent crude measures of risk to exposed populations.

[17/] Quoted from IRLG, "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks," 44 FR 39858, 39871-72 (6 July 1979).

Table II-11. Summary Assessment of Applicator Risk, Present Use Patterns

Use	Fetotoxicity Margin of Safety	General Acute Toxicity Margin of Safety	Cancer Probability Estimate Lifetime Risk*	Estimated # Persons Exposed	Remarks
Hardwood lumber	22	11	$2.6x10^{-2}$	2400	
Seed Treatment	28	14	$8.3x10^{-5}$	130,000	
Avocado Groves	7	4	$6.2x10^{-4}$	275	
Ornamentals					
1. Homeowner Use	94	47	$2.4x10^{-5}$	75,000	
2. Commercial Use	31-12	16-6	$7.3x10^{-5}$ to $2.9x10^{-3}$	30-1200	
Cucurbits	2,500	1,250	$4.1x10^{-6}$	950	
Christmas Trees	75-4	37-2	$3.7x10^{-5}$-$6.8x10^{-4}$	10,000	Great variation possible
Pecans	7	4	$3.1x10^{-4}$	1200	
Forestry	36	18	$1.9x10^{-3}$	1000	Anticipated to be male workers
Livestock (Spray Dip)					
Beef	500	250	5.0x10-6	250,000	
Pork	416	208			
Structures					10,000-12,000 houses; all age groups exposed
1. Inhabitants	416	3	$4.6x10^{-4}$	40,000	
2. Applicators	5	3	$4.4x10^{-3}$ to $8.8x10^{-3}$	500-1000	
Pineapples*/	$4.5 x 10^{7}$	$2.3x10^{7}$	10^{-12}	1600	
Pets					
1. Pet anti-flea collars	$3x10^{6}$	$1.4x10^{6}$	$2x10^{-4}$	ND**	
2. Dog Wash					
a) Applicators	$2.5x10^{5}$	$1.3x10^{5}$	$2.4x10^{-7}$	130,000	
b) Post-Application	$1.4x10^{5}$-$4.5x10^{4}$	$0.7x10^{5}$-$2.2x10^{4}$	$7.0x10^{-6}$	15,000,000	

*/ Given the extremely high margins of safety for the threshold effects of fetotoxicity and acute toxicity, the Agency considers the presumption on pineapples rebutted for these two effects.

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Table II-11. Summary Assessment of Applicator Risk, Present Use Patterns (Cont.)

Use	Fetotoxicity Margin of Safety	General Acute Toxicity Margin of Safety	Cancer Probability Estimate Lifetime Risk*	Estimated # Persons Exposed	Remarks
3. Dog Shampoo					
a) Applicator	16,666	8,333	3.6×10^{-5}	ND**	
b) Post-Application	3,840	1,920	2×10^{-6}	ND**	
4. Dog Dust					
a) Applicator	83,000	41,666	1.5×10^{-5}	ND**	
b) Post-Application	9,260	4,630	1.9×10^{-5}	ND**	
Household Uses					
1. Shelf Paper	6,000	3,000	3.9×10^{-5}	11,000,000	All age groups exposed
2. Floor Wax	1,250	625	6.7×10^{-4}	100,000,000	All age groups exposed
3. General Purpose Household Spray	3.0×10^{7}	1.9×10^{7}	6.0×10^{-4}	ND**	All age groups exposed
4. Roach Fumigation Devices	700	350	1.1×10^{-3}	ND**	Anticipated for young children
Minor Uses					
1. Industrial Use Moth Spray				ND**	
- Application	4.5×10^{4}	2.2×10^{4}	1.3×10^{-6}		
- Post-Application	8×10^{4}	4×10^{4}	1.1×10^{-5}		
2. Uninhabited Buildings Insect Spray	135	60	1.9×10^{-6}	ND**	PCO only
3. Empty Storage Bin Fog Spray	39	20	5.5×10^{-4}	ND**	

* Lifetime Risk based on 40 years of exposure by this mode.
Cancer Assessment Group (CAG) estimate amended 16 August 1979.

Note: Some exposure assumptions may differ slightly from those used in the margin of safety (MOS) calculations.

** ND: Not Determined

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It should be emphasized that, as with the cancer risk assessment of lindane, considerable uncertainty surrounds the assessment of fetotoxic risk. The anticipated adverse effects of a pesticide vary with the extent of exposure associated with its various uses, and the Agency has necessarily made cautious and prudent assumptions concerning exposure. (Refer to Subsection II.B., "Exposure Analysis.") Because current methodologies permit only rough estimates of human risk and because of the serious public health consequences if the estimated risk were understated, it is likewise Agency practice to use the most conservative results from the animal data in making risk estimates for the human population.

Although fetotoxic effects are considered a chronic human risk, it should be pointed out that fetotoxicity can result from a single exposure. Hence the Agency is concerned about possible cases of both acute or subchronic exposure to pregnant women.[18/] The Agency's focus of concern is on the potential injury to the fetus resulting from the mother's exposure to lindane, whether such injury occurs in either the presence or in the absence of toxic signs in the mother. The data on lindane indicate that the pesticide has the potential to cause fetotoxic effects both in the absence and in the presence of maternal toxicity at dose levels close to human exposure levels. (Refer to Subsection II.A.2.)

Although Earl et al. (1973), which showed that lindane feeding at both 7.5 and 15.0 significantly increased the proportion of stillbirths to beagle dogs, stands unrebutted as evidence of the fetotoxic effects of the pesticide, the study did not determine a NOEL and therefore cannot be used as a basis on which to calculate margins of safety for fetotoxic effects. On the basis of the following studies, however, the Agency has been able to determine a NOEL of 5 mg/kg/day. Oral studies rather than available studies using the subcutaneous route were selected for risk assessment purposes because the oral route (gavage) is that route which has been historically and consistently used for risk evaluation, and the route specifically identified as the route of choice in the EPA Proposed Test Guidelines (Subpart F). Dermal toxicology, when done, often appears to exert excessive stress on a pregnant animal and poorly indicates the actual dose absorbed.

a. Palmer and Lovell [1971 (confidential;unpublished)], an oral fetotoxicity study involving female specific pathogen free rats: NOEL 5 mg/kg/day.

b. Palmer and Neuff [1971 (confidential; unpublished)], an oral fetotoxicity study involving New Zealand white rabbits: NOEL at least 5 mg/kg/day.

[18/] In connection with the various uses of lindane on pets, the Agency is also concerned about potential fetotoxic effects in cases of exposure to pregnant animals.

c. Bauer and Frohberg [1972 (confidential; unpublished)], an oral fetotoxicity study on MRI mice: NOEL 30 mg/kg/day.

d. Khera et al. (1979), a rat oral fetotoxicity study using 50 percent formulation expressed as active ingredient: NOEL 12.5 mg/kg/day.[19]

At doses greater than 5 mg/kg, the major fetal effect was an increase in skeletal variations (extra ribs) as compared to controls. This determination was complicated by the following two factors: (1) often the percentage of fetuses having an extra rib was within a so-called normal range of 8-41 percent (20 percent average) for CD rats and 25-75 percent (47 percent average) for New Zealand white rabbits;[20] (2) except in Khera et al. (1979), the litter was not used as the unit for statistical analysis. Because of the possibility that a disproportionate number of affected fetuses might belong to a single dam, the litter, rather than the entire number of fetuses per dose level, is the preferred unit for analyses. Approximate margins of safety for fetotoxicity as calculated by the Agency are presented, use by use, in Table II-11.

Given a total dietary exposure, under current use patterns, of 0.003 mg/kg/day, dietary risk of fetotoxic effects is estimated in terms of an approximate margin of safety of 800.

3. Risk: Acute and Subacute Central Nervous System Effects

Available studies in humans and in diverse species of animals (dogs, rats, rabbits, frogs, chickens) report notably parallel results in connection with the acute and subacute toxic effects of lindane. [Refer to Subsection II.A.4.c.(4) and Table II-5.] Lindane has been shown to have an affinity for the fat-rich (white) nerve tissue, where it accumulates and causes symptoms of acute and subacute poisoning which are typical of central nervous system (CNS) stimulation. Actual symptoms correlate closely with theoretical mechanisms as well as mechanisms observed *in vitro* in various nerve types. Laboratory and epidemiological evidence has been reinforced by clinical findings (including tissue residue analyses) in conjunction with the recent death of a two-and one-half month old infant who had been treated for scabies with a commercial lindane product. A 110 ppb concentration of lindane in the child's brain was established as the most probable cause of death.[21]

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[19] Palmer and Lovell (1971), Palmer and Neuff (1971), and Bauer and Frohberg (1972) were submitted by Hooker Chemicals during the rebuttal period. (Refer to Table II-3.) Khera et al. (1979), an additional study discovered and reviewed by the Agency during the rebuttal period, is addressed in Subsection II.A.2.f above.

[20] Palmer, A.K. Sporadic Malformations in Laboratory Animals and their Influence on Drug Testing Advances. Exp. Med. & Biol. 27 (1972):45-60.

Symptoms in animals appear in the following order: 1) increased respiratory rate, 2) restlessness, 3) intermittent muscle spasms, 4) salivation, 5) disequilibrium, 6) convulsions, 7) collapse, and 8) death. Symptoms of acute poisoning in humans are similar to those displayed in laboratory animals and occur in this order: 1) dizziness, 2) headache, 3) nausea and vomiting, 4) diarrhea, 5) tremors, 6) weakness, 7) convulsions, 8) dyspnea, 9) cyanosis, and 10) circulatory collapse.

Based on Hayes (1963), the Agency has determined an approximate no observable effe[illegible] level (NOEL) in adult humans of 2.5 mg/kg/day. To recapitulate, Hayes [illegible]rved the following results when 100 percent gamma isomer (lindane) w[illegible]ted in humans: 0.66 mg/kg/day x 14 days--no effect: 2.3 mg/kg/day x [illegible]-no effect: 3 mg/kg/day repeated--dizziness and diarrhea after sever[illegible]. These findings correlate closely with the reported findings of Desi [illegible], in which dosages of 2.5 mg/kg/day administered to Wistar rats induced no pathological effects but triggered increased irritability as measured in performance tests.

A NOEL of 2.5 mg/kg/day for adult humans is inevitably a rough approximation, and the following points should be emphasized:

a. Effects at low dosage levels may be reversible.

b. Subtle, sub-symptomatic effects may occur below 2.5 mg/kg/day, and these changes could affect the functional efficiency of nerve transmission.

c. Among adults there may be a high degree of variation in sensitivity to the CNS effects of lindane.

d. Sensitivity in the young may be considerably greater than that of adults (Hanig et al., 1976).

Thus a NOEL of 2.5 mg/kg/day may well be underrepresentative for certain subgroups of the population, especially children, who might be particularly sensitive to the toxic effects of lindane.[22] It should be pointed out also that workers whose functions call for a high degree of nerve-motor coordination might experience decreased efficiency at unspecifiable doses below 2.5 mg/kg/day.[23]

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[21] Other lindane-related deaths have been reported, but only in connection with this recent instance were the results of tissue analyses available. [Refer to Subsection II.A.4 above and Hayes (1963).]

[22] In connection with the various pet uses of lindane, the Agency is also concerned about the potential acute effects of lindane to young animals.

Acute and subacute CNS risk to humans has been evaluated by comparing a 2.5 mg/kg/day NOEL with the highest estimated daily acute exposure for each use of lindane. The resultant margins of safety (MOS) represent rough measures of risk to exposed adult populations. (See Table II-11.) Based on available data, specific margins of safety for children could not be calculated but are likely to be considerably lower than those estimated for adults.

Given a total dietary exposure, under current use patterns, of 0.003 mg/kg/day, dietary risks of CNS effects are estimated in terms of an approximate margin of safety of 1600.

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[23] For the pineapple use, the margin of safety for acute and fetotoxic effects is sufficiently high (2.3×10^7) and (4.5×10^5), respectively, that the possibility of adverse effects and acute and fetotoxic effects is extremely slight. Under Agency regulations, a presumption for an acute effect may be rebutted when it is shown that the pesticide "when considered with the formulations, packaging, method of use, and proposed restrictions on and directions for use and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional or national populations of nontarget organisms is not likely to result in any significant acute adverse effects" [subsection 162.11(a)(iii)(4)(i)]. A chronic effect presumption such as fetotoxicity may be rebutted "when considered with the proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist or accrue to levels in man or the environment likely to result in any significant chronic effects" [subsection 162.11(a)(4)(ii)]. In view of the exceptionally high margin of safety for the acute and fetotoxic effects for pineapples, the rebuttable presumption against registration for these effects on the pineapple use has been rebutted.

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III. BENEFIT ANALYSIS

A. Introduction

Material presented in this section is based primarily on an in-depth Preliminary Benefit Analysis of Lindane (PBA) (EPA 1978f); it is not based on an alternative version prepared by USDA in October, 1979. The approach taken in this joint EPA/USDA effort was to evaluate the economic benefits of lindane [illegible] terms of the economic impacts which would result if lindane uses were cancelled, and users were forced to employ available alternatives.[1] Economic impacts were calculated at the user level on a use-by-use basis. Impacts at the commodity and consumer levels were then projected, where appropriate. The analysis was based on the most recent data available (1975-1977). Estimated impacts are expressed in 1977 dollars. However, data on the extent of pest problems and pest control methods are exceedingly limited. This necessitated a number of assumptions in connection with the potential total effects of cancelling lindane. Therefore the estimates are rough approximations and subject to revision if data become available.

As Table III-1 shows, three uses account for 87 percent of an approximate total of 901,000 to 937,000 pounds of lindane used each year in the U.S.: seed treatment (48 percent), hardwood lumber (22 percent), and livestock (17 percent). The major economic impact from the cancellation of lindane would fall in the hardwood logs and lumber industry. A major impact is possible in connection with lindane seed treatment, but data limitations have precluded any assessment in quantified terms. Moderate impacts are estimated for the ornamental, cucurbit, and Florida avocado industries. In general, minor impacts are projected in the forestry and Christmas tree industries, although individual growers could experience major impacts. All other users, including livestock farmers, would experience only minor economic impacts. Should all uses of lindane be cancelled, total quantifiable yearly impacts are estimated at $181,000,000.

The projected major and minor impacts derive primarily from a lack of adequate alternatives to lindane. For some uses, there are no known alternative control methods for the target pests. For some other uses, the alternatives are reported to be ineffective or to affect product quality.

B. Underlying Assumptions and Limitations

In addition to specific limitations noted in the individual analyses presented in the subsections below, certain general limitations were common to all analyses of lindane uses. These are as follows:

1. Published data or experimental results identifying yield changes were generally unavailable. Therefore, expert opinions of knowledgeable persons familiar with lindane use served as the bases of economic impacts.

2. Published data specifying alternate insect control strategies for each use were unavailable. Expert opinion was used to generate impacts of alternate control strategies.

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[1] Alternatives were identified from lists of EPA-registered pesticides.

Table III-1. Summary of Benefit Analysis

Use Site	Extent of Use		Availability of Economic Alternatives	Impacts			
				Economic			
	A.I. pounds and (%)*	Treatment Units (# Units)		Nature	Extent ($/year)	Significance	Social Community
Hardwood Lumber	200,000 (22%)	3,365,705,000 board ft	None	Yield & quality loss	$147,020,000	Major	
Seed Treatment (small grains and corn)	426,000 (46%)	13,089,000 acres small grains; 3,800,000 acres corn	None for small grains; several for corn	Yield loss for small grains, lentils, and dry peas	Not quantifiable except for corn ($690,000)	Possible major impact for small small grains, lentils, and dry peas; minor for corn	
Avocados	7,000 (1%)	7,000 acres	None for mirids; several for webbing worm	Yield and quality loss	8,700,000	Moderate	Regional impact in Florida
Ornamentals (commercial and household uses)	17,000 (2%)	3,630 acres	No alternatives for most pests	Production cost increase & yield loss	20,600,000	Moderate	Regional impacts on landscape configuration; property losses to homeowners
Cucurbits	11,000 (1%)	11,600 acres	Alternatives exist with varying levels of efficacy	Production cost increase & yield loss	176,000	Minor	
Christmas Trees	Unknown	Unknown	Chemical alternative for white pine weevils only; cultural alternatives not evaluated	Production cost increase & yield loss	Not quantifiable	Major to some individual growers; aggregate impact not estimated	Possible regional hired labor impacts, particularly in the Lake States

* Due to rounded calculations, percentages add up to 99.6 percent total.

Table III-1. Summary of Benefit Analysis (Cont.)

	Extent of Use			Impacts			
				Economic			
Use Site	A.I. pounds and (%)*	Treatment Units (# Units)	Availability of Economic Alternatives	Nature	Extent ($/year)	Significance	Social Community
Pecans	33,600 (4%)	440,000 trees	Alternatives exist with varying efficacy	Production cost increase & yield loss	$1,374,000	Minor	
Forestry	4,000 (0.5%)	Unknown	Alternatives only partly replace lindane in forest mgmt	Yield & quality	Not quantified	Minor	
Livestock	140,000 - 176,000 (17%)	20,122,000 head	Alternatives generally available & efficacious	Production cost increase	$1,083,000	Minor	
Structures	1,000 (0.1%)	10,000 homes	Equally effective alternatives exist	Possible cost increase	Near zero	Minor if PCP is available	Possible labor & community impacts if there are multiple adverse RPAR decisions
Pineapples	19,000 (2%)	9,650 acres	None to replace its role in dual treatments; DBCP & EDB offer some anti-symphylid control	Yield loss	$1,018,000 (4 years)	Minor	Possible labor & community impacts if there are multiple adverse RPAR decisions

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Table III-1. Summary of Benefit Analysis (Cont.)

	Extent of Use			Impacts			
				Economic			
Use Site	A.I. pounds and (%)*	Treatment Units (# Units)	Availability of Economic Alternatives	Nature	Extent ($/year)	Significance	Social Community
Pets 1) Pet Collars 2) Dog Wash 3) Dog Shampoo 4) Dog Dust	30,000 (3%)	Unknown	Several effective alternatives available	Possible cost increase	Near zero	Minor	
Household 1. Shelf Paper 2. Floor Wax 3. Household Spray 4. Fumigation Devices	12,000 (1%)	Unknown	Several effective alternatives available	Possible cost increase	Near zero	Minor	
Minor Uses 1. Moth Spray, Industrial Use 2. Insect Spray, Uninhabited Buildings	Unknown	Unknown	Alternatives likely to exist	Unknown	Unknown but likely minor	Unknown but likely minor	

Table III-1. Summary of Benefit Analysis (Cont.)

	Extent of Use			Impacts			
				Economic			
Use Site	A.I. pounds and (%)*	Treatment Units (# Units)	Availability of Economic Alternatives	Nature	Extent ($/year)	Significance	Social Community
3. Empty Storage Bin Fog Spray							
All Uses	900,600- 936,600				$180,868,000		

3. In cases of unknown insect activity levels, it was assumed that infestations were more severe in climates known to be conducive to the insect and less severe in inhospitable climates.

4. Because of the imprecise nature of the data used to determine effects on yields and prices, the analysis focused on direct impacts to users. No attempt was made to quantify impacts beyond this level.

C. Hardwood Logs and Lumber

1. Usage

Lindane, the gamma isomer of BHC, is registered for control of the following pests on logs and lumber: 1) bark beetles, including pine bark beetles; 2) wood-boring insects, including wood-boring beetles, flatheaded wood borers, round-headed wood borers, powderpost beetles, lyctus beetles, and ambrosia beetles. The powder-post and lyctus beetles are drywood pests only; the remainder attack logs and lumber only after the moisture content falls below 48 percent.

EPA is at present allowing lindane to be substituted for BHC, which has been cancelled, in products registered for use on logs and lumber. Mill owners are currently phasing in lindane as a substitute for BHC in their pest control programs. Due to the present changeover, actual figures for lindane use are unavailable. It is assumed, however, that lindane will entirely replace BHC. Consequently, the figures given in Table III-2 should be regarded as applicable to lindane per se, although they are expressed in terms of both lindane and BHC.

Data are unavailable on the extent to which lindane is actually used to treat lumber in sawmills. The estimates given in Table III-2 below have been developed by the Agency. The estimates presented do not include usage on hardwood logs because no data are available. Therefore, logs were not included in the benefit analysis. The remainder of this section deals exclusively with lindane application to lumber.[2]

2. Alternative Methods of Control

No chemical controls other than lindane are registered for application to green lumber to control ambrosia beetles or flatheaded and roundheaded borers, which are the pests of main economic importance to the hardwood sawmill industry. Copper naphthenate is registered to control powderpost beetles on lumber. Pentachlorophenol (PCP) is registered to control wood-boring beetles on logs and powderpost and lyctus beetles on lumber.[3]

2/ Refer to PBA (EPA 1978f), pp. 51-57.

3/ Pentachlorophenol is currently under RPAR review.

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Table III-2. Use (in Pounds) of Fortified BHC and Gamma Isomer to Treat Green Hardwood Lumber - 1975[a/b/]

Region of U.S.	High Estimate		Low Estimate		Mean Estimate	
	FBHC*	Gamma Isomer	FBHC	Gamma Isomer	FBHC	Gamma Isomer
North Central & Northeast	201,700	84,700	82,200	34,500	142,000	59,600
South	373,900	157,000	284,900	119,600	329,400	138,300
Total Eastern U.S.	575,700	241,700	367,000	154,200	471,400	198,000

*Fortified benzene hexachloride (FBHC) contains approximately 42-43 percent gamma isomer.

a/ The range presented in Table III-2 is based on the total estimated volume of lumber treated.

b/ According to the Bureau of Census (1976), 97 percent of hardwood produced in this country came from the Eastern U.S. as comprised of two regions: 1) the northeast and north central region (35 percent) and 2) the southern region (62 percent). As defined by the Bureau, the northeast and north central region consists of Maine, New Hampshire, Vermont, New York, New Jersey, Pennsylvania, Ohio, Indiana, Illinois, Michigan, Wisconsin, Minnesota, Iowa, North Dakota, Nebraska, and Kansas; the southern region consists of Delaware, Maryland, District of Columbia, Virginia, West Virginia, North Carolina, South Carolina, Georgia, Florida, Kentucky, Tennessee, Alabama, Mississippi, Arkansas, Louisiana, Oklahoma, and Texas.

For the most economically important hardwoods (oak, gum, cottonwood, hickory, and elm), which constitute 65 percent of the total hardwood production, there are no non-chemical control methods which do not reduce the lumber quality to below marketable levels. For other hardwoods, there are non-chemical methods including kiln-drying, and "end-racking" (rapid no-heat curing). End-racking produces warping and cracking which severely reduces lumber quality. Kiln drying introduces a 10-15 percent deterioration to those species which can be kiln dried. Kiln drying is most effective for northern hardwoods, principally maple, and is generally less effective for southern hardwoods where the insect problem is most severe. This coupled with the high cost of kilns makes this control method impractical.

3. Economic Impacts

According to the National Forest Products Association (NFPA), the hardwood sawmill industry is characterized by small family-owned mills (NFPA, 1977). These mills are generally each capable of producing 10,000,000 board feet of lumber annually.

Impacts from cancellation of lindane were estimated based on production costs of $163 per 1,000 board feet, gross revenue of $193 per 1,000 board feet, and estimates of loss provided by the NFPA. These impacts are shown in Table III-3.

Estimates of the total impact to the hardwood industry should lindane be cancelled are given in Table III-5. The impacts were calculated from the average loss figures shown in Table III-3 and the estimates of total lumber treated with BHC and lindane given in Table III-4. The estimates are presented in terms of ranges as well as most likely estimates.

Given the absence of chemical alternatives, and given the infeasibility of the limited non-chemical alternatives, the economic impacts experienced by the hardwood lumber industry are expected to be substantial should lindane be cancelled.

D. Seed Treatment (Small Grains, Corn, Lentils, and Dry Peas)

1. Usage

Lindane is registered as a seed treatment for small grains (wheat, barley, oats, and rye), corn, and other crops such as sorghum and a number of vegetables. Lindane is generally formulated in combination with a fungicide and applied to the seed as a planter box treatment.[4]

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[4] When plateless or air planters are used for corn, planter box treatments may become ineffective because of the loss of pesticide remaining on the seed (Bode et al., 1976). Air and plateless planters are more efficient than conventional plate planters. As the new air and plateless planters replace conventional planters, the acreage which could be effectively planted with planter box seed treatments will diminish.

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Table III-3. Expected Values ($) With and Without Chemical Pest Control of Hardwood Lumber Per 1,000 Board Feet a/

	Expected Value			Value Loss	
Species b/	Lindane or BHC Control	No Control Moderate Attack	No Control Severe Attack	No Control Moderate Attack	No Control Severe Attack
Red Oak	194.00	172.00	138.00	22.00	55.00
Sap Gum	153.00	141.00	120.00	12.00	33.00
Weighted Average	190.00	170.00	137.00	21.00	54.00

a/ Estimates were rounded to the nearest dollar.

b/ Species chosen were felt to be representative of all hardwood species.

Table III-4. Estimated Lumber Treated by Region in U.S. - 1975.

Region	Lumber Production 1000 bd. ft.	Estimated % Lumber Treated Min % treated	Max % treated	Mean % treated	Estimated Lumber Treated (1000 bd. ft.) min	max	mean
Northeast and North Central	1,778,500	33	81	57	586,900	1,440,600	1,013,700
South	3,178,300	64	84	74	2,034,100	2,669,800	2,352,000

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Table III-5. Economic Dollar Impacts on the Sawmill Industry [a]

Region	Per Average Mill		Total Per Region		Most Likely
	Minimum	Maximum	Minimum	Maximum	Total Impact
Northeast & North Central	119,027	306,001	21,168,900	54,244,000	21,168,900
South	154,526	395,966	49,113,900	125,851,100	125,851,100
Eastern U.S. Total	-	-	70,282,700	180,095,200	147,020,000

[a] Rounded to the nearest $100.

As a seed treatment, lindane is used to control wireworms, seedcorn beetles, and seedcorn maggots, sporadic pests which cause non-germination of seeds or weak seedlings. The treatments are made primarily as insurance against potential damage and afford protection to the seed and ensure germination. However, under high levels of soil pest infestation the seed treatment does not protect newly emerged roots or shoots which are also subject to attack by wireworms and additional pests.

As Table III-6 shows, approximately 426,000 pounds of lindane are used annually for seed treatment. Of that total, about 81 percent is used to protect small grain seed from the wireworm complex, and about 15 percent to protect corn seed from wireworms, seedcorn maggots, and seedcorn beetles. An additional 3 percent is applied to lentils and dry peas. Because small grain (primarily wheat), corn, lentil, and dry pea seed treatments comprise 99 percent of total lindane used for seed treatment purposes, this analysis focuses on these applications. Approximately 13.1 million acres of small grains are planted with lindane treated seed annually. Approximately 6.0 million acres representing 39 percent of North Dakota small grain acreage and 1.3 million acres or 55 percent of the Idaho small grain acreage are planted with lindane seed.

2. Alternative Methods of Control

Heptachlor is presently registered to control the same spectrum of pests as lindane on small grains and corn.[5/]. There are no other viable registered alternatives to lindane for small grains. However, viable alternatives are registered for seed treatment of corn. Diazinon is registered as a corn seed treatment to control seedcorn maggots and seedcorn beetles (and as a soil treatment to control wireworm). Chlorpyrifos is registered as a seed treatment to control seedcorn maggots, but it is not registered to control wireworms or seedcorn beetles. Other alternatives to control the soil insect complex in corn are available, but these are for soil application (pre-plant) and not as seed treatments.

3. Efficacy of Lindane Seed Treatment and Alternatives[6/]

The efficacy of lindane used a seed treatment has been demonstrated in numerous studies and for a variety of crops including small grains and corn. Studies were conducted by: Dogger and Lilly (1949), Hocking (1949), Owen (1950), Elmore (1953), Kulash (1953), Frost, Anderson and Elmore (1954), Hastings and Cowen (1954), Ditman, Cox and Kantzes (1955), Daniels (1955), Kulash and Monroe (1954 and 1955), Hoffmaster and Nugent (1956), Lilly (1956), Kulash (1956), Bowling (1957), Harwood, Nelson and Telford (1957), Apple, Strong and Raffensparger (1958), Long and

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[5/] The Final Order of the Administrator in the Chlordane/Heptachlor Cancellations (signed March 6, 1978) phases out this alternative, and heptachlor use on barley, oats, wheat, rye, and corn will be cancelled effective September 1, 1982.

[6/] Economic data summarized in this subsection have been developed supplemental to the Preliminary Benefit Analysis of Lindane (PBA 1978).

Table III-6. Estimated Annual Use of Lindane as a Seed Treatment, by Crop - 1976.

Crop	Lindane A.I. (Pounds)	Percent Used as a Seed Treatment
Small Grains	344,400	81%
Wheat	(250,400)	(59%)
Barley, oats and rye	(94,000)	(22%)
Corn	64,300	15%
Lentils and dry peas	11,000	3%
Other crops[a]	5,900	1%
Totals	425,600	100%

[a] Includes dry beans, sorghum, sunflowers, sugar beets, and vegetables.

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Lilly (1958 and 1959), and Bigger and Decker (1966). While the efficacy data support the effectiveness of lindane seed treatments at low to moderate levels of infestation, it has been shown that under heavy infestations of wireworms, wireworms not killed or repelled at planting time or during germination, may ultimately reach sprouts or seedlings (Kulash, 1953).

One of the most recent studies was conducted in Washington in 1977-1978. The study evaluated 20 different compounds as seed coatings to dry land wheat for control of wireworms. Only three compounds provided statistically significant increases in plant stand counts as compared to the control. These were: lindane, chlordane, and heptachlor (Perkins and Harwood, 1979).

Agriculture Canada has submitted unpublished test data to the Agency which evaluate the effectiveness of lindane seed treatments of cereal grains and rape. The test data spanning 1952-1976 show the effectiveness of lindane in reducing wireworm populations and improving stand counts (Burrage, 1980).

4. Economic Impacts

Very little biological information is available which is necessary to quantitatively estimate the economic impacts of a lindane seed treatment cancellation on small grains, lentils, and dry peas. Although the efficacy of lindane in improving stand counts and reducing wireworm damage has been quantitatively demonstrated, other critical information has not been developed. For example, information relating stand counts to yield losses is not available, nor is information relating yield losses with varying intensity of wireworm infestations in relevant geographic locations available. Data identifying the frequency of infestations exceeding the economic thresholds for various crops in various locations are not available, and data indicating the efficacy of lindane with varying levels of pest infestation have not been developed.

The lack of biological data on small grains, lentils, and dry peas has severely hampered economic impact analysis, since the expected value of yield losses over time cannot be estimated and alternative chemicals are not available to control the soil pests. Therefore, economic impacts can only be qualitatively estimated for these crops. In the case of corn, chemical alternatives are available and expected yield losses can be estimated; therefore quantitative economic estimates have been made.

Corn [7]

Lindane is applied to corn seed at a cost of approximately $0.15 per acre[8]. Diazinon seed treatments can be substituted for lindane seed treatments at a cost of approximately $0.20 per acre where seedcorn beetles and seedcorn maggots are the pests requiring control. The substitution of diazinon seed treatments for lindane seed treatments would result in increased chemical costs of $190,000 annually on the 3.8 million acres of corn planted with lindane treated seed.

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[7] Economic data summarized in this subsection have been developed supplemental to the Preliminary Benefit Analysis of Lindane (EPA 1978).

[8] All costs are in 1977 dollars.

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However, diazinon seed treatments do not effectively control wireworm damage. It is estimated that approximately 1 million corn acres or less are infested with wireworms annually. Most of this acreage is currently treated with soil insecticides. It is estimated that approximately 100,000 acres infested with wireworms would not be treated with soil insecticides and would be infested with wireworms resulting in yield losses. Yield losses are anticipated to average approximately 2 bushels per acre based on U.S. average corn yields of 93 bushels per acre (1976-1978) and a 1966 study performed in Illinois where an average yield increase of 2.2 percent was reported for the seed treated versus untreated plots (Bigger and Decker, 1966).

Assuming corn prices of $2.50 per bushel, yield losses combined with increased treatment costs would average approximately $5.05 per acre on the 100,000 wireworm infested acres. On the remaining 3.7 million acres increased costs of $0.05 per acre would be experienced. Aggregated user costs for the cancellation of lindane on corn seed are estimated at $690,000 per year. The level of production losses anticipated (less than .003 percent) is not expected to result in economic impacts at the market or consumer level.

Small grains

Growers are currently treating small grain seed with lindane at costs ranging from approximately $.20 per acre for winter wheat to $.46 per acre for barley. Lindane is applied to protect the seed from wireworm damage. There are no alternative chemicals available other than heptachlor for wireworm control for small grains.

For the reasons described at the beginning of this Economic Impacts section no quantitative analysis of impacts is possible. However, the potential for impacts can be described qualitatively. Should lindane be cancelled, economic impacts would most likely fall into two patterns:

a. Fields planted without pesticides and damaged by pest infestations might be replanted if timing and other environmental factors were favorable. The estimated cost of replanting an acre of wheat is about $12.00, including machine operation, labor, and seed. Replanted fields may also experience yield losses because of insects and less favorable germination and growing periods; the frequency and damage of these losses cannot be determined.

b. Insecticidal treatments would not be made and sporadic yield losses would result, but for any of a variety of reasons, the damaged area would not be replanted (the frequency and magnitude of these losses cannot be determined).

These two outcomes point to a potential for economic impacts on small grains currently planted with lindane-treated seed. Of the grains, spring-planted small grains could be seriously affected, and this would be felt most severely in North Dakota, Idaho, and Minnesota, where wireworm infestations are most severe and where 50 percent of spring-planted grains are grown. An estimated 12 percent of U.S. small grain acreage is planted with lindane-treated seed; however, as much as 30 percent of U.S. spring wheat acreage is planted with treated seed. In North Dakota and Idaho 30 percent and 55 percent of the small grain acreages are with lindane-treated seed, respectively. Should lindane be cancelled, and should extensive wireworm damage result, major regional impacts are possible for spring-planted small grains at the user level. If significant production losses were to occur, cancellation could also result in potentially major spring-planted small grain market level impacts. The Agency has not found nor have data been submitted to estimate the likelihood or magnitude of this occurrence.

Lentils and Dry Peas

Approximately 3 percent of lindane seed treatment formulations are applied to lentils and dry peas, crops which are commercially produced only in Idaho and Washington. About 85 percent of lentil acreage and 100 percent of dry pea acreage were planted with lindane-treated seed as insurance against wireworm damage.

No alternatives to lindane seed treatment are available for these two crops. Data on possible yield losses from wireworm infestations are not available. However, given the high percentage of lindane seed treatment on lentils and dry peas -- depending upon the extent of wireworm damage which might otherwise occur -- cancellation may result in economic impacts at the user and market levels. The Agency has not found, nor have data been submitted to estimate the likelihood or magnitude of this occurrence.

E. Avocados

1. Usage

Lindane replaced BHC on avocados after the cancellation of BHC and is used extensively in Florida to control mirids and webbingworms. Approximately 7,000 pounds of lindane are used on about 90 percent of the crop in Florida to control these pests. Florida avocado production currently represents roughly 22 percent of U.S. avocado production. Lindane is not used on avocados in California (the other domestic producer) because mirids are not pests of economic significance in that state.

2. Alternative Methods of Control

There are no registered chemicals for mirid control except lindane. Parathion is registered to control webbingworms. There are no non-chemical control methods which produce a marketable crop for the fresh avocado market.

Preliminary results of a nearly completed study indicate that acephate and permethrin are effective materials for mirid control. Neither is currently registered for this use. Permethrin seems to have residual effects equal to those of lindane. The residual effectiveness of acephate is reportedly much shorter.[9]

3. Economic Impacts

A lack of hard data exists with which to quantitatively evaluate fruit losses (downgrading or complete loss due to fruit drop) resulting from mirid damage in the absence of lindane. According to state experts, the economic impacts from cancellation are estimated as a possible loss of 70 to 80 percent of the Florida avocado crop, though loss of early varieties could approach 100 percent. Loss is a combination of physical damage and/or cosmetic scarring which can lower grade. While a percentage of damaged crops would be sold to avocado processors, this would not offset the loss incurred by diminished sales to the fresh avocado market. Currently, the processed fruit market absorbs only about 5 percent of Florida's avocado production.

According to local experts,[10] losses would approximate 22,000 tons of avocados at a cost to users of $8.7 million assuming no change in grading standards.[11] If these standards were relaxed the proportion of the loss attributed to cosmetic damage from mirids would be reduced.

The anticipated losses are strictly from lack of mirid control. As an alternative and anti-webbingworm pesticide, parathion causes no substantial economic impacts.

F. Ornamentals

1. Usage

Lindane is used on a variety of woody ornamentals and floral and foliage plants to control primarily borers, thrips, and leafminers. Actual usage data are unavailable, and the estimates submitted by Hooker Chemical (74,840 pounds), USDA (13,402 pounds), and the National Arborist Association (3,580 pounds) vary greatly. Moreover, the USDA estimate is based solely upon reported use in only 6 states.

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[9] NOTE: These are preliminary results of a laboratory study and not a small plot field trial.

[10] A. Baranowski, Florida State Dept. of Entomology; H. Goldweber.

[11] The grading standard for avocados is at 22 FR 6205.

2. Alternative Methods of Control

Lindane is the only pesticide presently registered to control all borers on all woody ornamentals. Chlorpyrifos and endosulfan are registered for borer control only on selected species of ornamentals. Alternate pesticides are generally available for the pests of floral and foliage plants presently controlled by lindane.

3. Economic Impacts

Because data were unavailable, a precise quantitative analysis could not be performed. Estimates of projected losses are shown in Table III-7. These estimates are taken from reports of the states which reported on the USDA information survey. Total impacts on the woody ornamental industry may total $20.6 million dollars. As a whole, this is expected to be of less than major significance to the industry. Impacts on individual firms could be sizable. Impacts on the floral and foliage industry are expected to be minor.

G. Cucurbits

1. Usage

Lindane is registered for control of various insect pests (including aphids, cucumber beetles [striped and spotted], cutworms, melonworms, pickleworms, squash bugs, squash vine borers, and white grubs) on cucurbits such as canteloupe, cucumber, pumpkin, squash, and watermelon. Lindane treatment is used on only 12 percent of America's fresh market cucurbits.

Data concerning lindane usage on cucurbits are available from only three states: Florida (total cucurbit acreage: 17,900 acres), South Carolina (total cucurbit acreage: 14, 600 acres), and Georgia (total cucurbit acreage: 10,500 acres)[12] (See Table III-8). Twenty-two percent of the total cucurbit acreage of these states was treated with cucumber and squash acreage in the U.S. As Table III-8 shows, the common practice is to apply lindane to cucurbits from one to eight times during the growing season. However, experts generally consider four applications per season to be sufficient.

2. Alternative Methods of Control

Pickleworms and squash vine borers are the target insects of main economic importance on cucumbers and squash. Seventeen pesticides other than lindane are EPA-registered for use against these pests on squash and cucumbers. USDA recommends carbaryl, endosulfan, and lindane.

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[12] Lindane may also be used in other states to control squash vine borers and pickleworms, but no pertinent data are available.

Table III-7. Summary of Annual Costs for States Requesting Use of Lindane on Ornamentals
(in 1,000 Units)

State	Lilac Borer on Lilac	Lilac Borer on Ash	Dogwood Borer on Dogwood	Birch Borer on Birch	Locust Borer on Locust	Other	Total
Pennsylvania							0
Ohio	0.065	0.583	135.3	599	7,991		8,724.5
Tennessee			1,798.9				1,798.9
Iowa							(No Data)
Oklahoma							0
Maryland	0.200	0.529	134.9	209			344.6
Indiana	4.7	0.373	1,022.4	2,807	794		4,628.5
Missouri							0
Georgia[a]							(No Data)
Kentucky				119.6			119.6
Arkansas							0
Idaho	-0.5			4,994			4,993.9
Total, All States							20,610.0

[a] Georgia reported a 5.9 million dollar annual loss, but supplied no supportive data.

Table III-8. Total Lindane-Treated Cucurbit Acreage, in Pounds A.I. and Cost — 1976-1977.

	State			
Item	Florida	South Carolina	Georgia	Total
Total Cucurbit Acreage	27,900	14,600	10,500	53,000
Total Cucurbit Acreage Treated with Lindane	2,790	800	8,000	11,590
Percent of Total Treated Acreage	10%	5.5%	76.2%	21.9%
Number of Applications	1-2	7-8	4	3.6
Pound of A.I. Used Per Application Per Acre	0.25	0.25	0.25	0.25
Ppounds A.I. Used	1,046	1,500	8,000	10,546
Insecticide Cost	$11,339	$16,260	$86,720	$114,319

According to state entomologists, most growers in Florida use carbaryl in combination with endosulfan and methomyl to control borers and pickleworms, and the same combination is probably used in Georgia. Methomyl is used in South Carolina. However, no data are available on the extent to which these alternatives to lindane are presently used, either on a state or on an aggregate U.S. basis. All of these alternatives, particularly carbaryl, are toxic to bees and could conceivably cause yield losses due to a loss of pollination.[13]

3. Economic Impacts

There should be no overall change in the U.S. production of cucurbits if lindane were cancelled. Only 12.2 percent of the fresh market cucumber acreage is treated with lindane. Experts from Florida and South Carolina, the two states with greatest cucurbit acreage, estimated that the use of alternative chemicals would not affect yield.

As Table III-9 shows, replacing lindane with carbaryl would result in slightly decreased annual production costs; replacing lindane with endosulfan would increase production costs slightly; and replacing lindane with methomyl would result in production costs that are approximately twice the costs of treating with lindane.

Florida and South Carolina entomologists report no anticipated yield loss if lindane were cancelled; Georgia entomologists in contrast, report potential yield losses of up to 25 percent. Assuming no yield loss in any states, estimated impact on cucurbit growers should lindane be cancelled is minor, $176,000, a figure derived from the cost of alternatives recommended by the states (see Table III-10). The estimate of economic impact, assuming a 25 percent yield loss in Georgia and a shift to state recommended alternatives is $2.4 million. The conflict in estimates is surprising because the target pests in all three states, namely pickleworms and squash vine borers, are the same.

Furthermore, Georgia, the state reporting a potential yield loss, is bounded on the north by South Carolina and on the south by Florida, two states reporting no anticipated yield loss. Hence, in terms of climate, soil conditions and other considerations, one would not expect Georgia to present a yield impact situation that would be very different from the other two states.

In the Agency's judgement, the projected yield loss for Georgia has not been substantiated by supporting documentation that would be sufficient to override the conclusion that the yield impact in Georgia should be similar to the situation in Florida and South Carolina. The Agency feels it must conclude that the impact of lindane's cancellation in Georgia would be very minor, until such time as the Agency is presented with substantial information to the contrary.

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[13] See PBA, pp. 408-420.

Table III-9. Treatment of Cost of Lindane and Alternatives for Control of Squash Vine Borer and Pickleworm on Cucumbers and Squash in Southeastern U.S.

Insecticide	Cost/Unit of Formulation	Cost/100 Gallons of Dilute Mix	Insecticide Cost/Acre Application	Insecticide & Application Cost/Acre	Number of Applications	Total Season Cost/Acre
Lindane (25% WP)*	2.71/lb.	2.71	2.71	5.33	4	21.32
Carbaryl (50% WP)	1.43/lb.	5.38	2.15	4.77	4	19.08
Endosulfan (50% WP)	4.25/lb. a.i.	3.19	3.19	5.81	4	23.24
Methomyl (1.8 lb. per gallon)	21.70/gal.	8.14	8.14	10.76	4	43.04

* WP = wettable powder.

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Table III-10. Estimated Total Change in Costs of Production and Revenue to Squash and Cucumber Growers in Florida, Georgia, and South Carolina - 1976-1977

Site/Pest and State	Estimated Total Change in Costs Using Alternatives
Cucumbers	
Florida	(-)$96
Georgia	$86,880
South Carolina	$32,580
Squash	
Florida	$3,183
Georgia	$54,060
Total	$176,607

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H. Christmas Trees

1. Usage

Lindane is used to control five major pests which attack Christmas trees (pine regeneration weevil, northern pine weevil, pales weevil, pine root collar weevil, and white pine weevil). Little data are available on the amount of lindane used in the Christmas tree industry, and responses to the USDA survey did not provide enough estimates on which to base assumptions of use. Therefore, this discussion addresses all issues qualitatively.

2. Alternative Methods of Control

Oxydemeton-methyl is registered for control of white pine weevil infestations of established stands of Christmas trees. No other pesticides are registered for control of the other insects which infest Christmas tree stands.

Non-chemical control methods are available for some insect pests, although at present they are not generally used because they are labor-intensive and costly. These include early pruning, cultural land clearing, removal of old stumps, and alternate planting sites. However, cultural practices, if carried out diligently, are expected to suppress the pests to an acceptable level.

3. Economic Impacts

Without usage data, quantification of overall impacts is not possible, but the following statements can be made. Generally, oxydemeton-methyl is about 1.2-2 times the cost per acre of lindane ($1.50 - 3.00 per acre versus $1.30 per acre) and increase in grower costs is $.20 - $1.70 per acre. Cultural controls (non-chemical) are costly insofar as they are labor-intensive, and the effectiveness of cultural control methods is based upon the availability of labor. Most growers are expected to employ alternate control methods (chemical or non-chemical) where feasible, or shift Christmas tree production to tree species (e.g. Douglas fir) which are less susceptible to pest damage. The most severe impacts from cancellation of lindane would be borne by a few individual growers who for various reasons are unable (because of climatic or planting site limitations) to adopt alternate controls or species of tree. No estimate can be made of the number of farms to which this could happen.

I. Pecans

1. Usage

In response to a recent USDA survey, seven states (Alabama, Arkansas, Georgia, Mississippi, Louisiana, Oklahoma and Texas) reported using lindane on pecan groves. The primary use is to control phylloxera.

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Although lindane is also registered to control shoot curculio on pecan trees, shoot curculio is not an economic threat to pecans and therefore no pesticides are used to control this pest. As shown in Table III-11, 33,000 pounds of lindane are used on 447,800 pecan trees. Collectively, these states represent 76 percent of the U.S. pecan production. No data were supplied by the states producing the remaining 24 percent of the pecans.

2. Alternative Methods of Control

Alternative feasible pesticides currently include malathion, oils, and endosulfan.[14] However, no data are available to determine the extent of use of any alternate chemical.

3. Economic Impacts

The comparable costs of treating pecans with lindane and the alternative chemicals of choice, namely endosulfan, oil (dormant), or malathion, are listed in Table III-12 and III-13. Growers who substitute endosulfan for lindane would experience decreased seasonal pesticide costs of 23 cents a tree. The use of oil (dormant) as an alternative for lindane would result in an increased seasonal cost of $1.18 per tree; malathion use would cost $7.00 more than lindane per tree each season.[15] The owner of a hypothetical 20-acre pecan grove with 12 trees per acre would save $55.20 if endosulfan were substituted for lindane; by using oil, the same owner would occur an additional cost of $283 over lindane. If malathion, the most expensive alternative, were used and all other variables of production remained constant, this owner would incur an additional cost of $1,685 per year.

Entomologists consider endosulfan to be as effective as lindane, and no yield losses are anticipated if endosulfan entirely replaces lindane. Endosulfan is registered for pecans under FIFRA 24(c) in Mississippi or Louisiana and has Federal registrations for other crops. In view of endosulfan's regulatory history, it is appropriate to consider endosulfan a viable, registrable alternative for lindane on pecans. The Agency expects that endosulfan would become, in most instances, the

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[14] Endosulfan is registered under FIFRA 24(c) in Mississippi and Louisiana.

[15] From pecan crop budgets developed at the University of Georgia, total fixed and variable costs per acre (excluding land and irrigation) are $538 per acre per year. Total costs to pecan growers would increase as much as 15.1 percent per acre per year, if an average 2.5 applications of malathion are used instead of lindane. Costs would increase 2.5 percent per acre using oil (dormant). And costs to growers in Mississippi and Louisiana would increase 0.1 percent per year using endosulfan.

Table III-11. Number of Pecan Trees, Lindane-Treated Pecan Trees, and Amount of Lindane Used, Selected States (Estimates for 1976)

State	Pecan Trees		Lindane-Treated Trees			Lindane Usage (a.i.) on Bearing and Non-bearing Trees
	Bearing + Nonbearing	Bearing**	Bearing + Nonbearing	Bearing	Bearing + Nonbearing	
	1,000	1,000	1,000	1,000	Percent	1,000 Pounds
Georgia	1,359	1,212	40.8	36.4	3	3.1
Mississippi	255	202	48.4	38.4	19	3.6
Oklahoma	532	421	42.6	33.7	8	3.2
Texas	1,549	1,171	232.4	175.6	15	17.4
Other*	836	567	83.6	56.7	10	6.3
Total	4,531	3,573	447.8	340.8		33.6
(Avg. Percent)					(11)	

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* Alabama, Arkansas, and Louisiana. Lindane usage data were not provided by these states. The Agency assumes that Lindane usage in these three states was equal to the weighted average of treated bearing and nonbearing trees as reported for the states of Georgia, Mississippi, Oklahoma, and Texas.

** Pecan trees do not bear fruit until approximately 10 years of age.

Table III-12. Treatment Costs of Various Insecticides for Control of Pecan Phylloxera in the Southeastern U.S. (Estimated for 1976)

Insecticide	Label Rate	Price per Unit a.i.	Cost Per Tree Per Application Material	Labor & Equipment	Total	Applications Per Season	Seasonal Cost Per Tree
	Per Tree	---------------Dollars			----------------	Number	Dollars
Lindane	0.075 pounds	15.00	1.13	0.55	1.68	1	1.68
Malathion	0.67 pounds	4.36	2.92	0.55	3.47	2.5	8.68
Oil(dormant)	0.7 gallons	3.30	2.31	0.55	2.86	1	2.86
Endosulfan	0.15 pounds	6.00	0.90	0.55	1.45	1	1.45

Table III-13. Annual Treatment Cost with Lindane Compared to Alternative Control Measures on Pecans, Selected States, for 1976

State	Annual Treatment Cost of Using Alternatives on Affected Trees					Increase in Cost
	Lindane	Malathion	Oil	Endosulfan	Total	Compared to Lindane
	$1,000					
Georgia	68.5	354.1	---	---	354.1	285.6
Mississippi	81.3	---	---	70.2	70.2	(-11.1)
Oklahoma	71.6	138.9	30.3	---	169.2	97.6
Texas	390.4	---	531.7	---	531.7	141.3
Other States*	140.4	112.8	129.0	16.1	257.9	117.5
Total	752.2	605.8	691.0	86.3	1,383.1	630.9

*Alabama, Arkansas, and Louisiana. (See Table III-13.)

alternative of choice, considering that it is lower in cost than lindane and equally effective. The impact of lindane's cancellation would be negligible if endosulfan were federally registered or if other states granted 24(c) registrations. The Agency believes it to be highly likely that endosulfan will be used as a substitute for lindane in those areas where lindane is presently used on pecans.

The Agency also has developed a second scenario based on the premise that endosulfan would not become more widely available. This analysis was based on information provided by State entomologists working from current registrations. These entomologists indicated that lindane would most likely be replaced with endosulfan in Mississippi, with malathion in Georgia, with malathion and oil in Oklahoma, and with oil in Texas. Under this scenario, total pest control costs would increase for these major states (and three minor use states) by approximately $63,000 if lindane were unavailable. If malathion is substituted for lindane in Georgia and Oklahoma, average yield losses of 25 percent to growers would be anticipated. The use of oil is estimated to produce yield losses of 33 percent in Okalahoma, and 2.5 percent in Texas.[16] Under this scenario, the lost production to growers would be $742,000. Overall loss to growers from increased costs and yield declines would be around $1.4 million.

J. Forestry

1. Usage

Lindane is used mainly on pines and conifers to control several types of beetles (e.g. Southern pine beetle, turpentine beetle, and mountain pine beetle). While lindane is presently not widely used, it is the only pesticide which is effective in controlling insects in trees already infested, and as such it serves as an option should other methods fail. Approximately 1,700 pounds of lindane were used in the U.S. for forestry uses (1975-1976 growing season). It is used primarily in the South by the U.S. Forest Service and cooperating state agencies.

2. Alternate Methods of Control

Alternate chemicals presently registered include endosulfan, ethylene dibromide,[17] dicrotophos, and chlorpyrifos. Additionally, cacodylic acid, a herbicide, is registered for killing trees, thereby creating "trap" trees for the beetles.[18]

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[16] These two production losses are not necessarily inconsistent in that the Texas figures are an average based on treated trees (which is greater than infested trees) while the Oklahoma estimate is based on an average of infested trees. In any case the economic impacts remain minor.

[17] Ethylene dibromide is under RPAR review.

[18] When beetles lay their eggs in cacodylic acid-treated trees, larvae are "trapped" because the dead trees do not provide sufficient food for their survival.

Non-chemical control methods are already used in forests to guard against infestation. Methods used are basically good silvicultural management (e.g. growing trees on favorable sites, thinning stands, preventing tree damage, and removing weak or damaged trees). Additionally, practices designed to suppress infestations (e.g. salvaging infested trees, cut and leave, and cut and burn procedures) are prevalent. Chlorpyrifos has been shown effective against southern pine beetle and other forest pests (USDA Forest Service, 1979). Non-chemical methods are also effective suppression techniques in all but severe infestations.

3. Economic Impacts

a. Commercial Forests

If lindane were cancelled, impacts would be felt primarily in the Southern forests. No impacts are expected in cooler climates since insects are not active there, and cultural, non-chemical control of insect pests is practiced.

Among southern forests, small private land owners would take the brunt of a cancellation, because this group relies heavily on chemical control and cannot generally afford labor-intensive cultural management practices prevalent on publicly owned or corporately owned land.

a. Seed Orchards and Gum Naval Stores

As a control method which can effectively impede the spread of infestations, lindane is considered an important control option by seed orchard owners and by producers of naval stores, primarily because their individual trees are highly valuable and the possibility of bark beetle infestation is considered a serious economic threat. It would appear that chlorpyrifos is at least as effective as lindane (USDA Forest Service, 1979). There are approximately 10,000 acres of seed orchard in the Southeast, the major area involved. Orchard seed has been valued as high as $1,000 per pound, whereas "wild" seed gathered from non-orchard trees is valued at about $35 to $50 per pound. Gum naval stores producers are also located in the Southeast. In 1976, producers in Georgia, Florida, Mississippi, and Alabama produced crops valued at $5.6 million. Naval stores production has declined as petroleum-based synthetics have been developed. Demand may increase, however, if petroleum becomes unreasonably expensive.

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Seed orchards are generally very well cared for, and outbreaks of beetle infestation are relatively rare. Lindane has not been reported used in recent years on either seed orchard or naval stores-producing trees. The value of lindane to both seed orchard owners and naval stores producers is as insurance against unpredictable and potentially devastating beetle attacks.

K. Livestock (Spray)[19]

1. Usage

As a livestock spray, lindane is registered for controlling numerous pests (e.g., fleas, flies, lice, mites, and ticks) on livestock (i.e., beef cattle, hogs and pigs, sheep, goats, and horses) and in livestock premises (e.g., barns, pens, sleeping quarters, and shelters). Lindane use patterns have fluctuated from year to year, but there has been a distinct decline between 1971, (416,000 pounds) and 1976 (176,000 pounds).[20] This decline is shown in Table III-14, which lists USDA estimates of lindane usage on livestock for 1964, 1966, 1971, and 1976.

2. Alternative Methods of Control

A total of 18 alternative chemicals to lindane are registered for the major livestock class/pest combinations.[21] Not all alternatives apply to each livestock class/pest combination, but there are more than ten alternatives for each combination, except for mites on hogs and pigs. (Only three alternatives are registered for this application, and one, methoxychlor, is registered for use only in combination with toxaphene or malathion.) The control of mites in general--not only on hogs and pigs, but also on other classes of livestock--is problematic because of a lack of efficacious alternatives to lindane.

Table III-15 lists estimates of alternative pesticides versus lindane used on livestock for 1964, 1966, 1971, and 1976.

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[19] Lindane is apparently very rarely used as a livestock dip, though it is registered for dip as well as spray applications.

[20] This decline is from USDA estimates. However, Hooker Chemical has reported usage for 1976 of 139,000 pounds, which supports the USDA estimates.

[21] The 18 alternatives are Carbaryl (Sevin), Chlorpyrifos (Dursban), Coumaphos (Co-Ral), Crotoxyphos (ciodrin), crufomate (Ruelene), Dioxathion (Delnav), Famphur (Warbex), Fenthion (tiguvon), Imidan/prolate, malathion, methoxychlor (marlate) [registered only in combination with malathion or toxaphene for mite control on hogs], Phenothiazine, pyrethrins (synergized), Rabon/Gardona, Ronnel (Korlan), trichlorofon (Dylox), Vapona (DDVP) and toxaphene (currently under RPAR review).

Table III-14. Quantity of Lindane Used by U.S. Farmers on Livestock in 1964, 1966, 1971, and 1976 (USDA)

Livestock	Use in 1,000-pounds Units			
Class	1964	1966	1971	1976
Beef Cattle	186	130	226	79
Hogs and Pigs	143	124	164	91
Dairy Cattle	19	24	14	3
Sheep	10	6	4	2
Poultry	2	5	5	*
Other	N/A	4	3	1
Total	360	293	416	176

* = Less than 500 pounds.
N/A = Data not available.

Table III-15. Quantity of Lindane Versus Alternative Pesticides Used by U.S. Farmers on Livestock in 1964, 1966, 1971, and 1976

Pesticide	1,000 Pound Units			
	1964	1966	1971	1976
Lindane	360	293	416	176
Toxaphene	4,703	3,670	4,575	2,376
Methoxychlor	1,200	1,509	1,988	2,368
Coumaphos	766	434	168	517
Ronnel	755	391	470	483
Malathion	602	735	652	1,104
Dioxathion	N/A	43	59	100

3. Economic Impacts

For beef cattle, the annual cost of lindane treatment ranges from $0.33 to $0.45 per animal; annual cost of alternative treatments ranges from $0.33 to $0.62 per animal. For hogs and pigs, the annual cost of lindane treatment ranges from $0.16 to $0.35 per animal; annual cost of alternative treatments ranges from $0.18 to $0.49 per animal. Should lindane be cancelled for livestock applications, pest control costs can be expected to increase slightly. Total annual increase in the continental U.S. is estimated at $1,083,400 ($233,600 for beef cattle, $849,800 for hogs and pigs). Because efficacious alternatives are available (except for mite control) and because the cost increase for alternatives is small (a maximum of $0.08 per animal per year), no effect on production yield or quality is expected, and no significant market impacts are anticipated, unless mites become an endemic problem in a herd. A recent report by the National Academy of Sciences recommends the use of lindane over any other insecticide including the organophosphates because control can be obtained with only one application. Other pesticides are not as effective and require multiple applications, which can lead to development of genetically-induced resistance (Langford, 1980).

L. Existing Structures (Powderpost Beetles)

1. The Nature of Powder Post Beetle Infestation

Powder post beetles live inside wood. Because of the slow pace of their reproduction and spreading, significant powder post beetle damage may not occur until after 15-30 years or more of infestation (Williams, 1979). Sometimes infestations of powder post beetles die naturally, and not all infestations cause economic damage requiring treatment.

2. Usage

Lindane is used to spot-treat existing structures, mainly houses, against wood-boring powder-post beetles (anobiids, lyctids, and bostichids) and drywood termites. Though the amount of lindane currently used to treat existing structures is uncertain, it is believed to be small (less than 1,000 pounds on 10,000 or 12,000 houses). Chlordane has been the chemical of choice for this application. However, this use of chlordane has been cancelled—though existing stocks can still be used legally. As a substitute for chlordane, lindane has a potential annual market of about 10,000 pounds for this purpose.

3. Alternative Methods of Control

As pointed out by several state extension services, infestation can be prevented, and presumably retarded, by the use of painted or otherwise, finished wood. In the event that wood is structurally damaged, threat wood can be replaced with sound wood, which can be painted or finished to prevent future infestations.

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Several chemical alternatives to lindane are, moreover, registered for use on existing structures, including copper naphthanate, methyl bromide, sulfuryl fluoride, creosote, creosote oil, and pentachlorophenol (PCP). PCP is the state recommended alternative to chlordane, which was cancelled for this use.

4. Economic Impacts

The economic impact of cancelling the structural use of lindane is likely to be extremely slight. Chemical treatment can generally be avoided by painting or otherwise finishing wood surfaces. Should chemical treatment be considered desirable, PCP is available as an effective and economically competitive alternative to lindane. The cost of the chemical used in a spot spray treatment for powder post beetles is, moreover, a small part of the treatment cost, and the total treatment cost with either PCP or lindane is comparable ($200-250) per home). For the chemical cost, lindane is applied at a rate of one gallon of 0.5 percent solution at a cost of 0.48 per 500 square feet, and PCP is applied at a rate of one gallon of 5.0 per cent solution at a cost of $5.95 per 500 square feet). If PCP remains available, no significant cost impacts to pest control operators are predicted in the event that the use of lindane as a spot spray treatment against powder post beetles is cancelled.

Finally, lindane use is basically limited to spot treatment application. In cases of very severe infestation, fumigation is the treatment method used. Methyl bromide and sulfuryl fluoride are used as fumigants and at the cost of $1,000-$2,000 per home.

M. Hawaiian Pineapples

1. Usage

Lindane is registered for use in Hawaiian pineapple production to help control symphylids, root-feeding insects which attack pineapple roots soon after planting. Lindane is generally used in combination with soil fumigants to aid in control of symphylids.

The Hawaiian Pineapple Growers' Association estimates that annual use of lindane on Hawaiian pineapples ranges from 18,000 to 48,000 pounds. Other sources report to EPA that 19,300 pounds is the estimate of annual use of lindane on Hawaiian pineapple fields. Hawaiian pineapple production is based on a 3- or 4-year production cycle, which generally includes two harvests and a fallow period of 2 to 12 months. Approximately 13,400 acres are planted each year, and in 1977 total pineapple acreage was 43,000 acres (down from 58,000 acres in 1972). Lindane is applied, at the beginning of the growing cycle, to approximately 9,650 acres each year, which represents about 72 percent of annually planted acreage and about 22 percent of total pineapple acreage.

2. Alternative Methods of Control

The following soil fumigants, which primarily control nematodes, can give some assistance in controlling symphylids: dibromochloropropane (DBCP), ethylene dibromide (EDB), Telone, and DD (a mixture of 1,3 dichloropropene, 1,2 dichloropropane, and related C_3 compounds).[22] Ground preparation is important in assuring symphylid control since fumigants will vaporize off the soil in improperly prepared or excessively moist soil. Fumigants do not have residual action and offer no protection against possible late infestations. Lindane is used primarily as additional protection to compensate for adverse soil conditions and late infestations. Insufficient data on the effectiveness of lindane and the probability of late symphylan infestation, however, render the true value of lindane difficult to confirm. At present, there is no non-chemical method of controlling symphylids.

3. Economic Impacts

Hawaiian Pineapple Growers' Association officials have estimated that if lindane were unavailable as an anti-symphylid treatment, and growers were thereby forced to rely on the various dual-purpose fumigants, the result would be an annual crop loss of about 0.8 percent (about 5150 tons of the annual crop), valued at $515,000 at the farm level. During a 4-year production cycle, the Hawaiian pineapple industry would have to absorb a loss, at present farm value, of $1,018,367.[23] However, no firm data are available to substantiate the estimate. This constitutes a minor impact on the pineapple industry. No consumer impacts are expected because foreign supplies are presently available, and price impacts from an annual crop loss of 5,150 tons would be negligible.

N. Pets

Lindane is registered for control of ticks, fleas, lice, and mites on dogs, cats, and their premises. Registered products include anti-flea cat collars, dog wash, dog shampoo, and dog dust.

1. Usage

Current data indicate that lindane is not widely used on pets and their premises. About 30,000 pounds are used annually to treat pets for parasite problems, including scabies (mange)-causing mites. In the concentrations necessary for parasite control, lindane is toxic to cats, but not to dogs. Only Ohio still recommends lindane for control of fleas on cats.

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[22] Chloropicrin is also registered as a dual-purpose soil fumigant but it is not reported used.

[23] None of this loss would be incurred the first year because the first pineapple crop untreated with lindane would not be harvested for 20 months, and growers would in fact save the estimated $88,000 spent each year for lindane. This annual saving has been factored into the estimated total 4-year loss of $1,018,367. Second-year losses would be $250,970, third-year losses $442,162, and fourth-year losses $413,235.

2. Alternative Methods of Control

There are 15 registered pesticide alternatives to lindane for control of insect pests on cats and dogs. The major alternates are carbaryl, coumaphos, pyrethrins, resmethrin and ronnel. However, none of these are reportedly effective against scabies-causing mites.

Several preventive, non-chemical methods also help control parasites which attack pets. Ticks on dogs can be discouraged if grass and weeds are kept mowed along paths and around pet premises. Owners of dogs and cats can control fleas by thoroughly vacuum-cleaning infested rooms, including carpets, rugs, upholstered furniture, and other items which may harbor eggs or larvae.

3. Economic Impacts

Lindane and its various alternatives are generally in the same price range. Should lindane be unavailable for use on pets, any economic impact would be too small to measure, and this holds for both short-term and long-term perspectives.

O. Household Uses

Lindane is registered to control the following household pests: ants, centipedes, clothes moths, house fleas, odorous house ants, cockroaches, bedbugs, gnats, little black ants, sowbugs, carpet beetles, mosquitoes, scorpions, spiders, waterbugs, and silverfish. Under the general category of household uses there are four major applications of lindane:

(1) Shelf Paper
(2) Floor Wax
(3) General Purpose Household Spray
(4) Smoke-Fumigation Devices

1. Usage

In its various applications as a household pest control, lindane is used by both commercial pest control operators and individual homeowners. Hooker Chemicals Company estimates that 31,971 pounds of lindane are used annually for household purposes (12,488 pounds for shelf paper and 19,483 pounds for other applications).[24]

2. Alternative Methods of Control

There are a number of chemical alternatives to lindane as a household pesticide. The most recommended alternatives include diazinon, malathion, naphthalene, paradichlorobenzene, methoxychlor, and dichlorvos.

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[24] USDA estimated 83,788 pounds of lindane a.i. used annually for household purposes. An EPA survey of pesticide use in households reported no use of lindane. EPA economists consider the Hooker estimate to be the best estimate available.

3. Economic Impacts

Because data on frequency of use and relative efficacy of lindane and its alternatives are not available, comparative costs of application could not be calculated. In general, however, effective, competitively priced alternatives to lindane products are available. Should use of lindane as a household pesticide be cancelled, no economic impacts are expected.

P. Minor Uses

(1) Moth Spray (Aerosol) - Industrial Use

(2) Uninhabited Buildings - Insect Spray

(3) Empty Storage Bin Fog Spray

The Agency received no responses from registrants or user groups to its request for information concerning the benefits of those minor uses listed above or any of the other registered uses for lindane. The Agency's review of the benefits of lindane uses also did not report any data on the benefits of these particular applications or the other uses. In the absence of such information, the Agency must proceed on the assumption that the benefits involved are negligible.

IV. Development of Regulatory Options

A. Introduction

In the previous Sections II and III, the human and environmental risks associated with the uses of lindane were examined, and the benefits associated with each use were identified insofar as data were available. As explained in Section 1, FIFRA mandates the Agency to achieve a balance between the competing considerations of risks and benefits. To carry out that mandate, the Agency has developed a range of regulatory options and proceeding on a use-by-use basis, has evaluated each option for its impacts on both sides of the risk/benefit equation.

This section of Position Document 2/3 briefly summarizes the salient risks and benefits associated with the uses of lindane and describes the process by which the Agency developed potential courses of action. Section V proceeds with a use-by-use analysis of the risk/benefit impacts of the regulatory options and explains the course of action which the Agency proposes to adopt and implement.

B. Salient Risk/Benefit Considerations

In performing a risk/benefit analysis of the uses of lindane, the Agency identified several salient factors, on both sides of the risk/benefit equation, which became determining considerations in the development of regulatory options. These considerations are reviewed below.

1. Salient Risk Factors

As detailed in Section II, two of the original risk criteria cited in the RPAR notice as bases for the Agency's presumption against lindane stand unrebutted and represent significant chronic human risks: (1) oncogenicity, and (2) reproductive/fetotoxic effects.[1] The studies which showed that lindane is oncogenic in mice constitute evidence that the pesticide poses a cancer risk to man. Likewise the studies which indicated that lindane causes fetotoxic effects in test animals are cause for concern that lindane is fetotoxic to humans. Because no lindane products are currently registered for direct aquatic application, the third presumption -- acute hazards to wildlife, aquatic species — has been withdrawn.

In addition to the risk criteria upon which the lindane RPAR was based, the Agency identified as areas of concern the following possible adverse effects of the pesticide and requested additional information: (1) mutagenicity, (2) blood dyscrasias, (3) acute hazards to humans and domestic animals, and (4) population reduction in nontarget avian species.[2]

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[1] Although fetotoxic effects are considered a chronic risk, it should be pointed out that fetotoxicity can result from a single exposure.

[2] The additional issue of chemical isomerization effects of lindane, also mentioned in the RPAR notice, is not a determining consideration for reasons given in Subsection II.A.4.e of this position document.

Concerning mutagenicity per se, the Agency has on the basis of available data determined that risk criteria warranting a rebuttable presumption have not been met. However, since indications of mutagenesis constitute indirect evidence of carcinogenicity, the positive responses observed in several studies lend qualitative reinforcement to the Agency's presumption of lindane's oncogenic effects.

Regarding lindane-related blood dyscrasias, the Agency has likewise determined that risk criteria warranting a rebuttable presumption have not been met. Although insufficient evidence exists to firmly establish a cause-effect relationship between lindane exposure and blood dyscrasias, the Agency remains concerned, however, that the hematopoietic tissues of certain individuals, particularly children, might be especially sensitive to lindane.

Regarding acute hazards as lindane-related adverse effects, the Agency is, as a result of further EPA research, concerned in particular about the acute effects of lindane on the central nervous system (CNS), especially with regard to children.[3/] Studies have come the Agency's attention which indicate that lindane bioaccumulates in the CNS, triggering symptoms of acute poisoning which are typical of CNS stimulation. The results of a recent study (Hanig et al., 1976) indicate further that young animals (weanling rabbits) are more sensitive to the CNS effects of lindane than are adults, and these results take on added significance in light of the recent fatal lindane poisoning of a child in Florida. Given this evidence, the Agency concludes that as a CNS stimulant, lindane poses a human risk and that this risk is particularly significant in cases of exposure of children.

Concerning population reduction in nontarget avian species as a possible adverse effect of lindane, the Agency has determined that risk criteria warranting a rebuttable presumption have not been met and that there is little evidentiary basis for concern.

3/ Additional Agency findings concerning the acute effects of lindane on the central nervous system are addressed in Subsection II.A.4.c.(4).

The Agency's concern regarding the potential for lindane to produce both acute and chronic effects in humans is heightened by the persistence of lindane in the environment. As residues of lindane can remain in the environment for a long time period, the potential duration of lindane exposure following application of the chemical presents a significant problem. The persistence of lindane poses a particular concern for home uses, such as structures, household uses and pets, where residents can experience substantial long-term exposure to lindane residues. Moreover, in general, there is concern about the bioaccumulation of lindane in humans and the burden this places on the body's systems in view of the widespread use of the compound and its mobility to sites far removed from the treatment areas.

The avenues of exposure to lindane are (1) dietary (oral), (2) dermal, and (3) inhalational. According to Agency calculations, a likely dietary exposure to the general population via lindane residues on food is 0.003 mg/kg per day.[4] This represents a lifetime oncogenic risk of 1.7×10^{-5} or roughly 17 potential cancers per million people.

Given established use patterns, the subgroups subject to dermal and inhalational exposure are pesticide applicators, both professional and non-professional, and persons who might be in the vicinity during or immediately after application. Again, special concern is warranted in connection with children, who may be more sensitive to the toxic effects of lindane than are adults. Workplaces and residences are the use sites of main concern.

Additionally, the Agency's concern about the environmental fate of lindane is further heightened by the lack of information on disposal methods for lumber dipping operations. The Agency believes that unless disposal methods preclude release of lindane into the environment there exists a potential for indiscriminate release of lindane whenever the machinery and tanks are cleaned of debris which occurs normally during the milling operations.

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[4] Agency calculations of dietary exposure to the general adult public are given in Subsection II.B.1.

2. Salient Benefit Considerations

The benefits of lindane were assessed in terms of economic impacts which would result if its uses were cancelled and users thereby forced to employ available alternatives. As detailed in Section III, should lindane be cancelled, the major economic impact may be expected to fall in the hardwood logs and lumber industry. Major impacts may occur in production of hardwood and ultimately consumer goods lumber, if cancellation occurs and if alternatives do not prove feasible.[5] Possible major impacts would occur for small grains; however, at this time the Agency does not have quantifiable data to support these impacts.

Moderate impacts are anticipated in connection with avocados, ornamentals and cucurbits. These moderate impacts on the local producer would have no expected significant impact on the nationwide production of avocados and cucurbits or the maintenance and production of ornamental trees and shrubs.

For all other uses of lindane minor to insignificant impacts are projected to the growers and producers. The Agency does not expect any measurable impact on nationwide production or prices of food, or any other facet of the agricultural economy.

The Agency anticipates that regulatory action short of cancellation will have no significant impact on the agricultural economy.

In the course of the Agency's benefit analysis, a general lack of effective alternatives to lindane emerged as a notable issue of concern. No alternatives to lindane are currently available for use on hardwood logs and lumber or in small grain seed treatment. Certain target pests of avocados, ornamentals, Christmas trees, forestry, and pineapples can be controlled by substitute chemicals, but no alternatives are registered which control all the pests of concern. For use on cucurbits and pecans, alternatives can be employed with varying levels of efficacy. For scabies-causing mites on pets and mites on livestock no completely effective alternatives are registered.

The Agency's analysis of benefits was hampered to a great extent by inadequate quantifiable data. Data limitations were especially problematic in connection with seed treatment, the major use of lindane. The Agency was unable to project potential yield losses (except for corn) and no quantitative estimate of the economic impacts of a seed treatment cancellation could be made. Quantifiable benefit data were unavailable also in connection with two lesser uses of lindane, forestry and Christmas trees. Again for these two uses, assessment of benefits was limited entirely to qualitative terms.

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[5] Although potentially substantial impacts are possible in connection with a seed treatment cancellation, quantifiable benefit data are not available.

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C. Development of Regulatory Options

With regard to pesticide products containing lindane, three basic regulatory options have been developed for consideration:

1. Continue registration without restriction.
2. Continue registration but amend the terms and conditions of registration.
3. Cancel registration.

Cancellation of registration (Option 3) represents an absolute regulatory response, for it means that the sale or the distribution of the pesticide for the use at issue is unqualifiedly prohibited. Unrestricted registration (Option 1) likewise reflects an absolute regulatory response for it means that sale and distribution are unconditionally continued. Registration with amended terms and conditions (Option 2), however, represents a range of possible courses of action in that the specific terms and conditions of registration are formulated or modified by the Agency on a use-by-use basis.

The process of developing a full range of regulatory options by which a statutory risk/benefit determination with respect to pesticide products containing lindane might be achieved focused on means to reduce levels of human exposure to the pesticide. The Agency has assessed the various exposure situations at issue and has developed for consideration a number of specific measures by which exposure and risk might be reduced via amendments to the terms and conditions of registration. The general and use-specific measures discussed in the following subsections have been selected and reviewed based on both potential effectiveness and economic and practical feasibility.

Table IV-1 lists specific protective measures taken into consideration. Table IV-2 shows the reduction in total body doses anticipated in connection with these measures. Table IV-3 shows estimated reductions in risk.

Table IV-1. List of Protective Measures Considered, Use by Use*

Use	Items	Description	Effects on Exposure
Hardwood logs and lumber	Impermeable protective clothing	-Elbow-length neoprene gloves, boots, and aprons	-Dermal exposure to hands, arms, feet, and body avoided -Respiratory exposure not altered
Seed treatment	Protective clothing, Paper masks	-Long-sleeved work shirts, long pants -Gloves to be used during mixing -Disposable paper masks to be used during mixing	-Dermal exposure to arms, legs, and hands avoided -Some reduction in dermal exposure to face -Inhalation of dust particulates eliminated
Avocados	Protective clothing and Impermeable gloves; or Roof-type shelters	-Long-sleeved work shirts, long pants -Wide-brimmed hats -Elbow-length neoprene gloves -Or roof-type shelters on machinery employed	-Reduction of dermal exposure to arms, legs, and hands -Some reduction of dermal exposure to head, face, and neck area -Respiratory exposure not altered
Ornamentals			
1. Homeowners	Protective Clothing, Impermeable gloves	-Long-sleeved work shirts, long pants -Elbow-length neoprene gloves	-Reduction of dermal exposure to arms, hands,and legs -Respiratory exposure not altered
2. Commercial Applicators	Protective clothing, Impermeable gloves, Respirators	-Long-sleeved work shirts, long pants -Elbow-length neoprene gloves -Respirators	-Reduction of dermal exposure to arms, hand, legs, and hands -Reduction of dermal exposure to face -Elimination of respiratory exposure
Cucurbits	Protective clothing	-Long-sleeved work shirts, long pants	-Reduction of dermal exposure to arms and legs

Table IV-1. List of Protective Measures Considered, Use by Use (Cont.)

Use	Items	Description	Effects on Exposure
Christmas Trees	Protective clothing, Impermeable gloves, boots, aprons	-Long-sleeved work shirts, long pants -Elbow-length neoprene gloves, boots, and aprons	-Dermal exposure to hands, arms, feet, and body avoided -Respiratory exposure not altered
Pecans	Protective clothing, Impermeable gloves; or Roof-type shelters	-Long-sleeved work shirts, long pants -Elbow-length gloves -Wide brimmed hats -Or roof type shelters on machinery employed	-Reduction of dermal exposure to arms, legs, and hands -Some reduction of dermal exposure to head, face, and neck area -Respiratory exposure not altered
Forestry	Protective clothing, Impermeable gloves	-Long-sleeved work shirts, long pants -Elbow-length neoprene gloves	-Reduction of dermal exposure to face only -Respiratory exposure not altered
Livestock	Protective clothing, Impermeable gloves, boots, aprons	-Long-sleeved work shirts, long pants -Elbow-length neoprene gloves, aprons, and boots	-Dermal exposure to hands, arms, feet, and body avoided -Respiratory exposure not altered
Structures			
1. Inhabitants	None applicable	-None applicable	-None
2. Applicators	Protective clothing, Impermeable gloves, Respirators	-Long-sleeved work shirts, long pants -Elbow-length neoprene gloves -Respirators	-Dermal exposure only to portion of face -Respiratory exposure avoided

Table IV-1. List of Protective Measures Considered, Use by Use (Cont.)

Use	Items	Description	Effects on Exposure
Pineapples	None Applicable	None Applicable	None
Pets			
1. Dog Washes			
a. Applicators	Protective clothing, Impermeable gloves and apron	-Long-sleeved work shirts, long pants -Elbow-length neoprene gloves -Neoprene aprons	Dermal exposure reduced to hands, forearms, and torso
b. Post Application	None Applicable	None Applicable	None
2. Flea Collars, Dog Shampoos, and Dog Dusts	None Applicable	None Applicable	None
Household Uses	None Applicable	None Applicable	None
1. Shelf Paper			
2. Floor Wax			
3. General Purpose Household Spray			
4. Smoke Fumigation Devices			

Table IV-1. List of Protective Measures Considered, Use by Use (Cont.)

Uses	Items	Description	Effects on Exposure
Minor Uses	None Considered	None Considered	None
1. Moth Spray, Industrial Use			
2. Insect Spray, Uninhabited Buildings			
3. Empty Storage Bin Fog Spray			

Table IV-2. Impact of Protective Measures on Total Body Doses to Applicators

Use	Dermal Uptake%	Dermal mg/kg/day	Respiratory mg/kg/day*	Total mg/kg/day	Annual Total mg/kg/yr
Hardwood	10%	0.048	0.012	0.06	15
Seed Treatment	1%	0.0113	-	1.13×10^{-2}	1.1×10^{-2}
Avocados	10%	0.667	0.01	0.677	1.35
Ornamentals					
Homeowners	10%	0.01	3×10^{-3}	0.013	0.013
Comm. Applicators	10%	0.02-0.06	-	0.02-0.06	0.02-0.86
Cucurbits	10%	0.00014	5.0×10^{-5}	2×10^{-4}	8×10^{-4}
Christmas trees	10%	0.009-0.269	0.27-0.04	0.036-0.31	0.04-0.37
Pecan Orchards	10%	0.15	0.013	0.163	0.163
Forestry	10%	0.09	0.03	0.12	3.5
Livestock	10%	0.003	$7 \times 10^{-4} - 8 \times 10^{-4}$	2.8×10^{-3}	2.8×10^{-3}
Structures					
Applicators	10%	1.35	-	0.135	2.7
Occupants	-	-	0.012	0.012	1.008
Pineapples	-	-	1.1×10^{-7}	1.1×10^{-7}	1.1×10^{-7}
Pets					
Pet Collars	-	-	1.0×10^{-6}	1.0×10^{-6}	6.6×10^{-4}
Dog Wash					
Applicators	10%	0.00004	-	0.00004	0.01
Post Application	-	-	3.6×10^{-5} 1.1×10^{-4}	3.6×10^{-5} 1.1×10^{-4}	2.8×10^{-3} 8.4×10^{-3}

*100% Respiratory uptake assumed
Refer to Table II-10. Total Body Doses (Applicators), Present Use Practices

Table IV-2. Impacts of Protective Measures on Total Body Doses to Applicators (Cont.)

Use	Dermal Uptake	Dermal mg/kg/day	Respiratory mg/kg/day*	Total mg/kg/day	Annual Total mg/kg/yr
Dog Shampoo					
Applicators	10%	2.3×10^{-3}	-	4×10^{-5}	0.01
Post Application	-	-	7.2×10^{-6}-2.1×10^{-5}	7.2×10^{-6}-2.1×10^{-5}	5.6×10^{-5} 1.6×10^{-3}
Dog Dust	1%	8×10^{-4}			
Applicators			4×10^{-5}	8.4×10^{-4}	0.021
Post Application	-	-	5.4×10^{-4}	5.4×10^{-4}	0.042
Household uses					
Shelf paper	-	-	8×10^{-4}	8×10^{-4}	0.084
Floor Wax	-	-	4×10^{-3}	4×10^{-3}	1.46
Household Spray	-	-	1.3×10^{-7}	1.3×10^{-7}	1.3×10^{-7}
Fumigation Devices	-	-	6.8×10^{-3}	6.8×10^{-3}	2.5
Minor uses					
Bath spray					
Indus. use					
Spray	-	-	1.1×10^{-4}	1.1×10^{-4}	2.7×10^{-3}
Impregnated Materials	-	-	6×10^{-5}	6×10^{-5}	2.3×10^{-2}
Insect Spray, Uninhabited Buildings	-	-	0.037	0.037	0.4
Empty Storage Bin Fog Spray	-	-	0.120	0.120	1.5

*100% Respiratory uptake assumed
Refer to Table II-10. Total Body Doses (Applicators), Present Use Practices

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1. General (Non-Use-Specific) Measures

The following measures have been considered in connection with the broad spectrum of lindane uses.

a. Require Label Warnings for All Uses of Lindane

Under FIFRA, the Agency may require that precautionary and warning statements appear on pesticide labeling. Given the oncogenic, acute toxic, and fetotoxic risks of lindane, and given the special sensitivity of children to the toxic effects of the pesticide, the Agency considers additional label warnings to be a reasonable precautionary measure. Therefore, the following warnings are proposed as label precautions for pesticide products containing lindane.

Label Warning

The United States Environmental Protection Agency has determined that lindane causes cancer and fetotoxic effects in laboratory animals, and central nervous system effects in both humans and laboratory animals.

Users:	Because lindane is highly toxic, extreme care should be exercised in handling this product. [Use of this product is limited to certified applicators only. Users are required to wear all recommended protective clothing. Protective clothing should be laundered separately, and all users should shower thoroughly after handling this product. Do not use lindane products on pregnant or young animals.][6]
Women:	Women of child-bearing age should not be involved in the mixing, loading, or application of this product. Exposure to lindane during pregnancy must be avoided.
Parents:	Children are very sensitive to the toxic effects of this pesticide. Avoid use in areas where children might be exposed.

b. Classify Lindane for Restricted Use and Require Applicator Certification.[7]

Under FIFRA, hazardous pesticides may be classified for restricted use and limited to use only by certified applicators. This measure would remove lindane from the open market and restrict its use to certified applicators and persons under their direct supervision. Classified for restricted use, lindane product would be available only to those users who have in fact undergone a certification program. Such programs are designed to encourage greater responsibility on the part of applicators and thereby reduce exposure and adverse effects, and are administered primarily by the states.

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[6] Bracketed material would be included as appropriate for those uses of lindane for which applicator certification and protective clothing requirements are imposed and/or those uses which involve livestock or pet applications.

[7] Not considered in connection with household uses, home pet uses, or homeowner uses on ornamentals.

All applicators would be required to obtain certification. If implemented this measure would have a negligible effect on benefits. All states currently have certification programs. Non-certified applicators would have to make minimal investments in certification courses.

2. Use-Specific Measures

a. Hardwood Logs and Lumber

Require that applicators wear impermeable (neoprene) aprons, boots, and elbow-length gloves.

Three principal lindane treatment methods are used in the hardwood logs and lumber industry: 1) green chain dip vat, whereby freshly sawed boards are completely immersed prior to stacking; 2) green chain spray, whereby the lumber is conveyed through a "spray booth" equipped with a low-pressure spray system; and 3) lumber "package dip vat," whereby packages of stacked lumber are immersed into a vat, then allowed to drain. These procedures take place in a covered but open plant.

As workers assist in guiding, pulling, and stacking the lumber, they are subject primarily to dermal but also to respiratory exposure to lindane. Exposure is estimated at 31,950 mg/yr (dermal) and 180 mg/yr (respiratory). At this level of exposure, cancer risks are estimated at 2.6×10^{-2} and margins of safety at 11 (acute effects) and 22 (fetotoxicity).

Measures short of cancellation by which exposure and risk to workers in the hardwood logs and lumber industry might be reduced were considered by the Agency based on their potential to reduce levels of dermal exposure, the primary source of risks to lumber plant workers. Because non-impermeable clothing could easily become saturated due to the application methods involved with this use, only impermeable clothing could measurably reduce dermal exposure. The Agency has determined that requiring workers to wear elbow-length impermeable (neoprene) gloves, impermeable aprons, and impermeable boots would reduce dermal exposure to the hands, trunk, and legs, which are the crucial points of contact. The estimated reduction in risks to be achieved via these risk-reduction measures are given in Table IV-3. However, it should be pointed out in this connection that according to the USDA, workers who handle treated lumber are already provided with rubber gloves, aprons or rain suits, and boots. Subsequent inspection of some sites by EPA revealed that not all workers wore this protective gear.

Table IV-3. Impacts of Protective Measures on Applicator Risk

Use	Risk Reduction Measures	MARGIN OF SAFETY: Fetotoxicity, Before	MARGIN OF SAFETY: Fetotoxicity, After	MARGIN OF SAFETY: General Acute Toxicity, Before	MARGIN OF SAFETY: General Acute Toxicity, After	CANCER PROBABILITY ESTIMATED LIFETIME RISK: Before	CANCER PROBABILITY ESTIMATED LIFETIME RISK: After	ESTIMATED PERSONS EXPOSED
Hardwood Logs and Lumber	Impermeable Protective Clothing	22	83	11	42	2.6×10^{-2}	6.9×10^{-3}	2400
Seed Treatment (small grains and corn)	Protective Clothing, Paper Masks	28	440	14	220	8.3×10^{-5}	5.0×10^{-6}	130,000
Avocados	Protective Clothing, Impermeable gloves; or Roof-type shelters	7	31	4	15	6.2×10^{-4}	2×10^{-6}	275
Ornamentals								
1. Homeowner Use	Protective Clothing, Impermeable Gloves	94	385	47	192	2.4×10^{-5}	6.0×10^{-6}	75,000
2. Commercial Use	Protective Clothing, Impermeable Gloves, Respirators	31-12	250-83	16-6	125-42	7.3×10^{-5} - 2.9×10^{-3}	8.8×10^{-6} - 4.1×10^{-7}	30-1200
Cucurbits	Protective Clothing	2,500	25,000	1,250	12,500	4.1×10^{-6}	4.0×10^{-7}	950
Christmas trees	Protective Clothing, Impermeable gloves, aprons, boots	75-4	139-16	37-2	70-9	3.7×10^{-5} 6.8×10^{-4}	2.0×10^{-5} 1.7×10^{-4}	10,000

Table IV-3. Impacts of Protective Measures on Applicator Risk (Cont.)

Use	Risk Reduction Measures	MARGIN OF SAFETY				CANCER PROBABILITY ESTIMATED LIFETIME RISK		ESTIMATED PERSONS EXPOSED
		Fetotoxicity		General Acute Toxicity				
		Before	After	Before	After	Before	After	
Pecans	Protective Clothing, Impermeable gloves; or Roof-type shelters	7	31	4	15	3.1×10^{-4}	7.5×10^{-5}	1200
Forestry	Protective Clothing, Impermeable Gloves	36	42	18	21	1.9×10^{-3}	5.5×10^{-4}	1000
Livestock	Protective Clothing, Impermeable Gloves, Boots, Aprons	416	1,786	208	893	5.0×10^{-6}	1.3×10^{-6}	250,000
Structures Inhabitants	None Applicable	416	416	3	3	4.6×10^{-4}	4.6×10^{-4}	10,000 - 12,000 houses
Applicators	Protective Clothing Impermeable Gloves, Respirators	5	37	3	18	4.4×10^{-3} 8.8×10^{-3}	1.2×10^{-3} 2.5×10^{-3}	
Pine-apples	None Applicable	4.5×10^{7}	4.5×10^{7}	2.3×10^{7}	2.3×10^{7}	10^{-12}	10^{-12}	1600

Table IV-3. Impacts of Protective Measures on Applicator Risks (Cont.)

		MARGIN OF SAFETY				CANCER PROBABILITY ESTIMATED LIFETIME RISK		ESTIMATED PERSONS EXPOSED
		Fetotoxicity		General Acute Toxicity				
Use	Risk Reduction Measures	Before	After	Before	After	Before	After	
Pets								
1. Dog Washes								
a. Applicators	Protective Clothing, Impermeable Gloves and aprons	2.5×10^5	1.2×10^6	1.3×10^5	6.2×10^5	2.4×10^{-7}	4.8×10^{-8}	130,000
b. Post Application	None Applicable	1.4×10^5	1.4×10^5	0.7×10^5	0.7×10^5	7.0×10^{-6}	7.0×10^{-6}	15,000,000
2. Other								
a. Flea Collars	None Applicable	3×10^6	3×10^6	1.4×10^6	1.4×10^6	2×10^{-4}	2×10^{-4}	Not Determined
b. Dog Shampoos	None Applicable							
1. Applicators		16,666	16,666	8,333	8,333	3.6×10^{-5}	3.6×10^{-5}	Not Determined
2. Post application		3,840	3,840	1,920	1,920	2×10^{-6}	2×10^{-6}	

Table IV-3. Impacts of Protective Measures on Applicator Risks (Cont.)

Use	Risk Reduction Measures	MARGIN OF SAFETY: Fetotoxicity Before	MARGIN OF SAFETY: Fetotoxicity After	MARGIN OF SAFETY: General Acute Toxicity Before	MARGIN OF SAFETY: General Acute Toxicity After	CANCER PROBABILITY ESTIMATED LIFETIME RISK Before	CANCER PROBABILITY ESTIMATED LIFETIME RISK After	ESTIMATED PERSONS EXPOSED
c. Dog Dusts	None Considered							Not Determined
1. Applicators		83,000	83,000	41,666	41,666	1.5×10^{-5}	1.5×10^{-5}	
2. Post-application		9,260	9,260	4,630	4,630	1.9×10^{-5}	1.9×10^{-5}	
Household Uses								
1. Shelf Paper	None Considered	6,000	6,000	3,000	3,000	3.9×10^{-5}	3.9×10^{-5}	Not Determined
2. Floor Wax	None Considered	1,250	1,250	625	625	6.7×10^{-4}	6.7×10^{-4}	Not Determined
3. General Purpose Household Spray	None Considered	3.8×10^{7}	3.8×10^{7}	1.9×10^{7}	1.9×10^{7}	6.0×10^{-11}	6.0×10^{-11}	Not Determined
4. Smoke Fumigation Devices	None Considered	700	700	350	350	1.1×10^{-3}	1.1×10^{-3}	Not Determined

Table IV-3. Impacts of Protective Measures on Applicator Risks (Cont.)

Use	Risk Reduction Measures	MARGIN OF SAFETY: Fetotoxicity Before	MARGIN OF SAFETY: Fetotoxicity After	MARGIN OF SAFETY: General Acute Toxicity Before	MARGIN OF SAFETY: General Acute Toxicity After	CANCER PROBABILITY ESTIMATED LIFETIME RISK Before	CANCER PROBABILITY ESTIMATED LIFETIME RISK After	ESTIMATED PERSONS EXPOSED
Minor Uses								
1. Industrial Use Moth Spray	None Applicable							
a. Applicators		8×10^4	8×10^4	4×10^4	4×10^4	1.3×10^{-6}	1.3×10^{-6}	Not Determined
b. Post-application		800	800	400	400	1.1×10^{-5}	1.1×10^{-5}	Not Determined
2. Uninhabited Buildings Insect Spray	None Applicable	135	135	68	68	1.9×10^{-6}	1.9×10^{-6}	Not Determined
3. Empty Storage Bin Fog Spray	None Applicable	39	39	20	20	5.5×10^{-4}	5.5×10^{-4}	Not Determined

b. Seed Treatment

Require that applicators wear long-sleeved workshirts and long pants, and gloves and disposable paper masks during mixing.

In applying lindane products to seeds, applicators are exposed to airborne lindane dust particles generated during pouring and mixing of seed powder mixtures, whether by hand or mechanically. Dermal and respiratory exposure incurred by applicators are estimated at 306 mg/yr and 7.8 mg/yr, respectively. At this level of exposure, cancer risks are estimated at 8.3×10^{-5} and margins of safety at 14 (acute toxicity) and 28 (fetotoxicity).

Measures short of cancellation by which exposure and risk to applicators might be reduced were selected for consideration based on their potential to reduce levels of dermal and respiratory exposure. Due to the method of preparing the lindane mixture for use, inhalation of dust particulates could be eliminated by the use of either a respirator or a paper mask. Because respirators are not only expensive but impractical for seed treatment application practices, paper masks were selected for consideration in the Agency's risk-reduction calculations. Crucial points of dermal exposure are the arms, legs, and hands of the applicator. Protective clothing requirements comprised of long-sleeved shirts, long pants, and gloves would reduce dermal contact to these crucial areas. The paper mask would also reduce dermal exposure to the face. The estimated reduction in risks to be achieved via these risk-reduction measures are given in Table IV-3.

c. Avocados and Pecans

1) Require that applicators wear long-sleeved work shirts, long pants, wide-brimmed hats, and impermeable (neoprene) elbow-length gloves; or

2) Require a roof-type shelter on machinery being employed.

Lindane is applied to pecan and avocado trees via a one-man air-blast or an air-delivery sprayer, once per year in pecans or twice per year in avocados. These procedures subject applicators to dermal and respiratory exposure to lindane estimated at 804 mg/yr and 1.2 mg/yr respectively for avocados and 396 mg/yr and 0.6 mg/yr for pecans. At this level of exposure cancer risks are estimated at 6.2×10^{-4} (avocados) and 3.1×10^{-4} (pecans) and margins of safety at 4 (acute toxicity) and 7 (fetotoxicity).

Measures short of cancellation by which exposure and risks to applicators might be reduced were considered by the Agency based on their potential to reduce levels of dermal exposure, the primary source of applicator hazard for these uses. Due to the spray application methods involved, crucial points of dermal exposure are the hands, arms, and legs of the applicator. The Agency has determined that requiring applicators to wear long-sleeved work shirts, long pants, a wide-brimmed hat, and impermeable gloves would reduce lindane contact with the crucial points of exposure, and would also reduce dermal exposure to the face, head, and neck areas. The estimated reduction in risks to be achieved via these risk-reduction measures is given in Table IV-3.

d. Ornamentals

1) Homeowner Use: Require that homeowners wear long-sleeved work shirts and long pants, and impermeable (neoprene) elbow-length gloves.

2) Commercial Use: Require that applicators wear long-sleeved work shirts, long pants, impermeable (neoprene) elbow-length gloves, and respirators.

For ornamental use lindane is applied as a dilution (0.5 percent w/w lindane in solvent) of a 20 percent lindane formulation via hand-held hydraulic or compressed-air sprayers. Use patterns for ornamentals vary greatly and the range of possible exposure varies with duration of spraying and the number of applications per season. These exposures range from 30 mg/yr(dermal exposure) and 0.18 mg/yr (respiratory exposure) for homeowners applying the chemical to a few trees once a year, to a range of 90 - 3,600 mg/yr (dermal exposure) and 0.54 - 21.6 mg/yr (respiratory exposure) for commercial nursery workers applying the chemical to a large number of trees over a 15-day period. This exposure range results in an estimated cancer risk to applicators of roughly 2.4×10^{-5}-2.9×10^{-3} and margins of safety of roughly 94 (fetotoxicity) and 47 (acute toxicity) for homeowners and from 31 - 12 (fetotoxicity) and from 16-6 (acute toxicity) for commercial applicators.

Measures short of cancellation by which exposure and risks to applicators might be reduced were selected for consideration based on their potential to reduce levels of dermal and respiratory exposure for this use. Due to the application method involved, crucial points of dermal exposure are hands, arms, and legs. Lindane is applied to ornamentals in the form of a spray, and protective clothing could reduce dermal exposure to these areas. The Agency has determined that requiring commercial and homeowner applicators to wear long-sleeved work shirts, long pants, and elbow-length impermeable gloves would reduce lindane contact with the crucial points of dermal exposure. Commercial applicators would have the added requirement of wearing a respirator, which would eliminate respiratory exposure and further reduce dermal exposure by protecting the face. Homeowner applicators would be exempt from this requirement due to the cost of the article and the short duration of their exposure to lindane. Table IV-3 shows the estimated reductions in risk which would be achieved via these risk-reduction measures.

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e. Cucurbits

Require that applicators wear long-sleeved work shirts and long pants.

For use on cucurbits lindane is applied with a row crop boom sprayer. This procedure subjects applicators to both dermal and respiratory exposure estimated at 0.42 mg/yr and 0.0126 mg/yr, respectively. At this level of exposure, cancer risks are estimated at 4.1×10^{-6} and margins of safety at 1,250 (acute toxicity) and 2,500 (fetotoxicity).

Measures short of cancellation by which exposure and risk to applicators might be reduced were considered by the Agency based on their potential to reduce levels of dermal exposure, the primary source of exposure and risk in connection with this use. Due to the application method involved, non-impermeable clothing could reduce dermal exposure. The Agency has determined that requiring applicators to wear long-sleeved work shirts and long pants would reduce dermal exposure to the arms and legs, which are crucial points of exposure. The estimated reduction in risks to be achieved via these risk-reduction measures is given in Table IV-3.

f. Christmas Trees and Forestry

1) Christmas Trees: Require that applicators wear long-sleeved work shirts and long pants, and impermeable (neoprene) aprons, boots, and elbow-length gloves.

2) Forestry: Require that applicators wear long-sleeved work shirts and long pants, and impermeable (neoprene) elbow-length gloves.

For use on Christmas trees and in forestry lindane is applied either by small back-pack sprayers or by small tractors pulling mini sprayers. These procedures subject applicators to dermal exposure estimated at 234 mg/yr (forestry)and 28.8 - 1,008 mg/yr (Christmas trees) and respiratory exposure estimated at 18 mg/yr (forestry) and 0.216 - 36 mg/yr (Christmas trees). At this level of exposure cancer risks are estimated at 1.9×10^{-3} (forestry) and 3.7×10^{-5} - 6.8×10^{-4} (Christmas trees). Margins of safety are estimated at 18 (forestry) and from 37 - 2 (Christmas trees) for acute toxicity and 36 (forestry) and 75 - 4 (Christmas trees) for fetotoxicity.

Measures short of cancellation by which exposure and risk to applicators might be reduced were considered by the Agency based on their potential to reduce levels of dermal exposure, the primary source of risks for these users. Due to the applicator methods involved, both non-impermeable and impermeable clothing are necessary to reduce dermal exposure. For use in forestry, crucial points of exposure are the hands, arms, and legs. To reduce dermal exposure to these areas the Agency has determined that applicators would have to wear long-sleeved work shirts, long pants, and elbow-length impermeable (neoprene) gloves. Christmas tree use of lindane poses added applicator exposure to the torso and feet. As a result the Agency has determined that applicators would be required to wear impermeable aprons and boots in conjunction with the risk-reduction measures stated above. The estimated reductions in risk to be achieved via these risk-reduction measures for forestry and Christmas tree use of lindane is given in Table IV-3.

g. Livestock

Require that applicators wear long-sleeved work shirts and long pants,and impermeable (neoprene) aprons, boots, and elbow-length gloves.

For use on livestock lindane is applied as an emulsion via pressurized spray to farm animals. This procedure subjects applicators to exposure estimated at 5.4 - 6.6 mg/yr (dermal exposure) and 0.06 mg/yr (respiratory exposure). At this level of exposure, cancer risks to applicators are estimated at 5.0×10^{-6}, and margins of safety at 416 (fetotoxicity) and 208 (acute toxicity).

Measures short of cancellation by which exposure and risk to applicators might be reduced were considered by the Agency based on their potential to reduce levels of dermal exposure, the primary sources of risks for this use. Due to the application method involved, the wearing of long-sleeved shirts and long pants, and impermeable neoprene gloves, aprons, and boots could viably reduce dermal exposure. The Agency has determined that requiring applicators to wear long-sleeved shirts, long pants, impermeable gloves, aprons, and boots would reduce dermal exposure to the hands, trunk, and legs, which are the crucial points of exposure. The estimated reduction in risks to be achieved via these risk-reduction measures is given in Table IV-3. The Agency also is in the process of evaluating suitable disposal or recycling requirements for the used lindane product. The Agency solicits comments in this area and will address it more specifically in PD 4.

h. Structures

1) Applicators: Require that applicators wear long-sleeved work shirts, long pants, and impermeable (neoprene) elbow-length gloves.

2) Inhabitants: Measures short of cancellation not practicable.

For use on structures lindane (0.5 percent w/w lindane in water) is applied with a paint brush for small areas or applied with a coarse spray for large areas. These procedures subject applicators to dermal and respiratory exposure estimated at 558 - 1,116 mg/yr and 18 - 36 mg/yr respectively. Inhabitants are subjected to respiratory exposure estimated at 60.48 mg/yr. At this level of exposure cancer risks are estimated at 4.4 x 10^{-3} - 8.8 x 10^{-3} (applicators) and 4.6 x 10^{-4} (inhabitants). Margins of safety are estimated at 3 (applicators and inhabitants) for acute toxicity and 416 (applicators) and 5 (inhabitants) for fetotoxicity.

Measures short of cancellation by which exposure and risk to applicators might be reduced were selected for consideration based on their viability as means to reduce levels of dermal and respiratory exposure. Crucial points of dermal exposure for applicators are the arms, legs, and hands. Protective clothing requirements comprised of long-sleeved shirts, long pants, and impermeable (neoprene) elbow-length gloves would reduce the dermal contact to these crucial areas. The estimated reduction in risks to be achieved via these risk-reduction measures are given in Table IV-3.

i. Pineapples

For use on pineapples lindane is applied by injection via hoses from a supply tank regulated by pressure valves into the soil at a depth of 8 to 78 inches under the planting line. Applicator exposure to lindane is possible only through inhalation of vapors. Dermal exposure does not occur since the application procedure prevents applicator exposure via splashing or mists. Respiratory exposure to lindane for applicators is estimated at 6.6 x 10^{-6} mg/yr. At this exposure level cancer risks are estimated at 10^{-12}. Because current application procedures already minimize exposure, no risk-reduction measures specific to this use were considered applicable.

j. Pets

1) Dog Washes: Require that veterinarian applicators wear protective clothing and impermeable (neoprene) aprons and elbow-length gloves.

This use of lindane subjects applicators to dermal exposure estimated at 0.0312 mg/yr; respiratory exposure is negligible. At this level of exposure, cancer risk is estimated at 2.4 x 10^{-7} and margins of safety at 2.5 x 10^{5} (fetotoxicity) and 1.3 x 10^{5} (acute effects).

Protective measures by which exposure and risk to veterinarian applicators might be reduced were selected for consideration based on their viability as means to reduce dermal exposure. Elbow-length impermeable (neoprene) gloves and impermeable aprons worn over protective clothing would reduce dermal exposure to the hands, forearms, and torso, the crucial points of contact. The reductions in risk anticipated via these measures are given in Table IV-3. For home applicators, risk reduction measures short of cancellation are deemed impracticable.

2) Flea Collar, Dog Dusts, and Dog Shampoo

Lindane flea collars, dog dusts, and dog shampoos are used primarily in the home by private pet owners. Risk-reduction measures short of cancellation are deemed impracticable.

k. Household Uses: Shelf paper, floor wax, general purpose household spray, and smoke fumigation devices.

In connection with lindane household products, risk-reduction measures short of cancellation are deemed impracticable.

l. Minor Uses

In connection with the various minor uses of lindane, no submissions concerning benefits have been received, nor have Agency efforts discovered any pertinent information. In the absence of data to the contrary, the Agency has necessarily assumed that the economic benefits involved are negligible. In view of the numerous, diverse minor uses at issue and the apparently negligible benefits involved, the development of use-specific risk-reduction measures short of cancellation is deemed impracticable.

V. Proposed Regulatory Decision

As stated in Subsection IV.C, the Agency has developed three basic regulatory options to be considered with respect to pesticide products containing lindane:

1. Continue registration without restriction.

2. Cancel registration unless the terms and conditions of registration are amended.

3. Cancel registration.

Subsection V.A below proceeds with a use-by-use analysis of the risk/benefit impacts of the regulatory options. Subsection V.B summarizes the course of action which the Agency proposes to adopt and implement.

A. Risk/Benefit Analysis of Regulatory Options, Use-by-Use

1. Hardwood Logs and Lumber

If registrations of lindane products for use in the hardwood logs and lumber industry were continued without restriction (Option 1), an estimated 2,400 applicators would continue to be exposed to lindane via dip or spray treatments. Cancer risks to these applicators would remain at an estimated 2.6×10^{-2}, and margins of safety would remain approximately 11 (acute toxicity) and 22 (fetotoxicity). Under Option 1 the benefits associated with this use, estimated at $147 million, would likewise continue unaffected.

If registrations of lindane for use in the hardwood logs and lumber industry were continued with amended terms and conditions (Option 2), the following provisions would apply. All pesticide products containing lindane would be classified for restricted use, and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindane products. Applicators would be required to wear impermeable protective clothing (elbow-length neoprene gloves, neoprene aprons, and neoprene boots). (Refer to Table IV-1.) Via these risk-reduction measures, cancer risks could be reduced from an estimated 2.6×10^{-2} to 6.9×10^{-3} and margins of safety increased from 11 to 42 (acute toxicity) and from 22 to 83 (fetotoxicity). (Refer to Table IV-3.) The provisions of Option 2 are expected to have a minimal impact on economic benefits.

If registrations of lindane products for use in the hardwood logs and lumber industry were cancelled (Option 3), all lindane-related risks to applicators would be eliminated. The economic impacts which would result from cancellation of this use are estimated at $147 million. Presently, no alternative chemicals are registered.

Having evaluated the cancer, acute toxic, and fetotoxic risks posed to applicators in conjunction with lindane use in the hardwood

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logs and lumber industry, the Agency has determined that continued, unrestricted registration (Option 1) is unjustifiable. Option 2 would be acceptable in this instance only if the reduced risks thereby achieved were decidedly outweighed by benefits. Given the substantial risks which would remain even if specified risk-reduction measures were implemented (Table IV-3), the Agency's determination is that Option 2 would fail to reduce risks to a level which would be outweighed by benefits and that cancellation (Option 3) is warranted.

While the prospective long-term risks outweigh benefits even when the provisions of Option 2 are taken into account, the following considerations lead the Agency to recommend cancellation to take effect after a phase-out/interim period. As discussed in Subsection III.C.2., no alternative chemicals are registered to control ambrosia beetles or flatheaded and roundheaded borers, which are the pests of main economic importance to the industry. Nor are non-chemical methods available which can viably control the target pests. Due to this lack of alternatives, economic impacts estimated at $147 million are expected to fall to the hardwood logs and lumber industry, which is characterized by a large number of small, family-owned mills. Impacts are expected to fall primarily to southern mills because that is where the insect problem is most prevalent. The possibility of mill closings is thereby raised.[1]

To encourage technological development of a suitable alternative(s) for use in the hardwood logs and lumber industry, and thereby to moderate the major economic impacts expected to result from an immediate cancellation, the Agency proposes cancellation to take effect after two years, during which time all of the amended terms and conditions of registration specified under Option 2 would apply. This time frame reflects the Agency's best judgment regarding the time period necessary to register an appropriate alternative. The Agency has received some information that chlorpyrifos is a pesticide whose biological activity is similar to lindane's and will provide adequate control for insect pests found in hardwood logs and lumber. Chlorpyrifos has been registered for use on live trees in forests and would therefore be expected to control target pests in felled trees and cut lumber.

FIFRA and related regulations require the Agency to consider both the risks and the benefits associated with the uses of pesticides. The proposed decision to cancel this use of lindane after two years, and in the interim to amend the terms and conditions of registration, represents the Agency's best determination, taking into account the risks and the benefits associated with lindane use in the hardwood logs and lumber industry. As discussed above, the major economic impacts expected in connection with an immediate cancellation can thereby be averted. Because exposure to applicators would be reduced from an estimated 40 years

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[1] PBA (EPA 1978f), p. 69.

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(estimated lifetime exposure) to 2 years, cancer risk to applicators wearing impermeable protective clothing would be reduced from 6.9 x 10^{-3} to 3.9 x 10^{-4}. Because during the 2-year phase-out/interim period, applicators would be required to wear the impermeable protective clothing specified under Option 2, margins of safety would be increased from roughly 11 to 42 (acute toxicity) and from 22 to 83 (fetotoxicity).

To recapitulate, the Agency proposes that lindane use in the hardwood logs and lumber industry be cancelled to take effect after two years in order to allow for the development/registration of a suitable alternative(s). During this 2-year phase-out/interim period, all of the amended terms and conditions of registration specified under Option 2 will apply.

2. Seed Treatments

If registrations of lindane products for use as a seed treatment were continued without restriction (Option 1), an estimated 130,000 applicators would continue to be exposed to lindane. Cancer risks to these applicators would remain at an estimated 8.3 X 10^{-5}, and margins of safety would remain approximately 14 (acute toxicity) and 28 (fetotoxicity). However, these calculations apply only to adults. Minors are commonly involved in seed treatment application practices. Because children are believed to be more susceptible to the toxic effects of lindane than are adults, the MOS for children in connection with acute effects is likely to be considerably lower. Under Option 1, the unquantifiable economic benefits associated with lindane use as a seed treatment would likewise continue unaffected.

If registrations of lindane for use as a seed treatment were continued with amended terms and conditions (Option 2), the following provisions would apply. All pesticide products containing lindane would be classified for restricted use, and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindane products. Applicators would be required to wear protective clothing (long-sleeved shirts, long pants, gloves, and disposable paper masks). (Refer to Table IV-1.) Via these risk-reduction measures, cancer risks could be reduced from an estimated 8.3 X 10^{-5} to 5.0 X 10^{-6}, and margins of safety increased from 14 to 220 (acute toxicity) and from 28 to 440 (fetotoxicity). (Refer to Table IV-3.) The provisions of Option 2 are expected to have a minimal impact on economic benefits.

The Agency's evaluation of the impacts of cancellation (Option 3) of lindane seed treatment has been hampered by the lack of benefits information submitted by the U.S. Department of Agriculture and other interested groups. Nevertheless, certain conclusions can be drawn. For corn acreage, diazinon is an inexpensive alternative that is effective against most corn pests, and hence adverse economic impacts in corn are not expected to occur. For small grains and other crops, the benefits situation is more problematical; given the lack of alternatives. On account of the lack of biological information, the Agency has been unable to predict with any confidence the likelihood of infestation or the loss from given levels of infestation, assuming no pesticide treatment. The Agency does believe, however, that based on the way in which lindane works to protect the unsprouted seed, it is basically an insurance treatment and, as such, is unlikely to be effective where heavy infestation occurs. Hence the risks posed by corn seed treatment strongly outweigh the small benefits for that crop.

For the remaining seed treatment uses, the regulatory decision is a difficult one. After careful consideration the Agency has concluded that the risks of use on these crops even reduced by protective measures outweigh the benefits of use insofar as the benefits are presently known and therefore recommends cancellation. The Agency invites the agricultural community and other interested groups during the comment period to focus particular attention on the benefits of lindane seed treatment on small grains, dry peas and lentils and the potential of developing alternatives. The Agency will reevaluate its proposed decision in light of the comments received.

Having evaluated the cancer, fetotoxic, and acute toxic risks posed to applicators as well as the dietary cancer risk to the general public in conjunction with lindane use as a seed treatment, the Agency has determined that continued, unrestricted registration (Option 1) is unjustifiable. Option 2, which would continue registrations with amended terms and conditions, would be acceptable in this instance only if the reduced risks thereby achieved were decidedly outweighed by benefits. Given the unquantifiable benefits associated with this use, however, and given the substantial risks, including a dietary cancer risk (Table II-6), which would remain even if specified risk-reduction measures were implemented, an Agency determination that the benefits associated with lindane seed treatment are of sufficient magnitude as to outweigh risks would be highly speculative in basis.[4] The Agency has therefore

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[2] Data in the Agency's possession indicate that neither diazinon nor chlorpyrifos poses unreasonable adverse effects.

[3] Registrations of heptachlor are being phased out on the basis of carcinogenicity.

[4] The Agency points out that the burden of proof with respect to the benefits of a pesticide as used for its intended purpose lies with the registrants. A general lack of data concerning the frequency of wireworm infestation and comparative data concerning the extent of crop damage and yield loss attributable to the target pests, with and without lindane seed treatment, contributed to the proposed cancellation. Any additional information submitted to the Agency will be taken into account in the final decision to be issued in Position Document 4.

determined that Option 2 is unacceptable and that cancellation (Option 3) is warranted. The Agency recommends that Option 3 be implemented with the call for additional information and cancellation of registrations of lindane products for use as a seed treatment is hereby proposed.

3. Avocados

If registrations of lindane products for use on Florida avocados were continued without restriction (Option 1), an estimated 275 applicators would continue to be exposed to lindane via high-exposure spray treatments. Cancer risks to these applicators would remain at an estimated 6.2×10^{-4}, and margins of safety would remain very low: approximately 4 (acute toxicity) and 7 (fetotoxicity). Under Option 1, the economic benefits, estimated at $8.7 million associated with lindane use on Florida avocados would likewise continue unaffected.

If registrations of lindane for use on avocados were continued with amended terms and conditions (Option 2), the following provisions would apply. All pesticide products containing lindane would be classified for restricted use, and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindane products. Applicators would be required either to wear protective clothing (long-sleeved shirts, long pants, and wide-brimmed hats) and impermeable gloves or to employ a roof-type shelter on machinery being used. (Refer to Table IV-1.) Given the climate conditions of Florida, however, whether protective clothing would in fact be worn is admittedly questionable. Via these risk-reduction measures, cancer risks could theoretically be reduced from 6.2×10^{-4} to 2×10^{-5}, and margins of safety increased from 4 to 15 (acute toxicity) and from 7 to 31 (fetotoxicity). (Refer to Table IV-3.) The provisions of Option 2 are expected to have a minimal impact on economic benefits.

If registrations of lindane products for use on avocados were cancelled (Option 3), all lindane-related risks to applicators as well as a cancer dietary risk would be eliminated. The economic impacts which would result from cancellation of this use are estimated, based on the projections of local experts, at $8.7 million and would be experienced by Florida growers,[5] assuming no change in grading standards. Although no chemical alternatives are currently registered for mirid control, several promising alternatives (such as acephate) are undergoing testing. Preliminary indications suggest that these chemicals may prove efficacious for mirid control. Parathion, presently used only in California, is available for control of webbingworms. Anticipated losses are strictly from lack of mirid control. Because California produces almost 80 percent of the nation's avocados,[6] no impact on the availability of avocados nationwide is expected, and should the grading standard for avocados be amended there could be no significant impact resulting from cancellation.

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[5] As noted in Subsection III.E.3, this estimate relies heavily upon information provided by persons with expertise in Florida avocado production and assumes that their projections of crop loss are accurate. No data are available concerning the extent of yield loss attributable to mirids, with and without lindane spray treatments.

Having evaluated the cancer, fetotoxic, and acute toxic risks posed to applicators in conjunction with lindane use on avocados, the Agency has determined that these risks are unacceptably high and that continued, unrestricted registration (Option 1) is unjustifiable. Option 2, which would continue registrations with amended terms and conditions, would be acceptable in this instance only if the reduced risks thereby achieved were decidedly outweighed by benefits. Given the high level of exposure associated with this use of lindane, however, substantial risks would remain even if the specific provisions of Option 2 were implemented. Also these low margins of safety and high cancer probability are not offset by firmly substantiated benefits attributable to lindane as an anti-mirid pesticide.[7] The Agency has therefore determined that Option 2 is unacceptble and that cancellation (Option 3) is warranted. Option 3 is hereby recommended, and cancellation of registrations of lindane products for use on avocados is proposed.

4. Ornamentals

If registrations of lindane products for use on ornamentals were continued without restrictions (Option 1), an estimated 30-1,200 professional applicators and an estimated 75,000 homeowner/applicators would continue to be exposed to lindane via spray treatments to control borers, thrips, and leafminers on a variety of floral and foliage plants and woody ornamentals. Cancer risks to these applicators would remain at an estimated 2.4×10^{-5} (homeowners) and 7.3×10^{-3} to 2.9×10^{-3} (commercial users), and margins of safety would remain approximately 47 for homeowners and 6-16 for commercial users (acute toxicity) and 94 for homeowners and 12-31 for commercial users (fetotoxicity). However, these calculations apply only to adults. Margins of safety for acute effects in children involved in application processes are likely to be considerably lower. Under Option 1, the economic benefits associated with lindane use on ornamentals, roughly estimated at $20.6 million for commercial growers of ornamentals, would likewise continue unaffected.

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[6] Pesticide use by California avocado growers is very limited, and California has not reported using lindane in avocado groves.

[7] The Agency is aware that the Agricultural Research and Education Center of the University of Florida is currently conducting pesticide field trials on the avocado/mirid/lindane issue. The experiments are scheduled for completion in June, 1980. Any data concerning the benefits of lindane as used for its intended purpose as an anti-mirid pesticide will be considered by the Agency and taken into account in the final decision on lindane to be issued in Position Document 4.

If registrations of lindane for use on ornamentals were continued with amended terms and conditions (Option 2), the following provisions would apply. For commercial use, all pesticide products containing lindane would be classified for restricted use, and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindane products. Commercial applicators would be required to wear protective clothing, impermeable gloves, and a respirator. Via these risk-reduction measures cancer risks for commercial applicators could be reduced from an estimated $7.3 \times 10^{-5} - 2.9 \times 10^{-3}$ to $4.1 \times 10^{-7} - 8.8 \times 10^{-6}$ and margins of safety could be increased from 6-16 to 41-125 (acute toxicity) and from 12-31 to 83-25 (fetotoxicity). (Refer to Table IV-3.)

For home use, homeowner/applicators would be required to wear protective clothing (long-sleeved shirts and long pants) and elbow-length impermeable gloves. Via these risk-reduction measures cancer risks to homeowner/applicators could be reduced from an estimated 2.4×10^{-5} to 6.0×10^{-6} and margins of safety could be increased from 47 to 192 (acute toxicity) and 94 to 385 (fetotoxicity). (Refer to Table IV-3.) The provisions of Option 2 are expected to have a minimal impact on economic benefits.

If registrations of lindane products for use on ornamentals were cancelled (Option 3), all lindane-related risks to applicators would be eliminated. The economic impacts which would result from cancellation of this use are estimated at $20.6 million to commercial growers of ornamentals. Impacts to homeowners would be largely aesthetic and such are not quantifiable. In areas where borer infestations are particularly problematic, homeowners might be forced to abandon certain species of woody ornamentals or to employ professional pest control.8/ Presently, lindane is the only pesticide registered to control all borers on woody ornamentals. Although alternative pesticides are generally available for pest control on floral and foliage plants, only two alternative pesticides, chlorpyrifos and endosulfan, are registered for borer control on woody ornamentals.9/ However, these two alternative pesticides are effective only on selected species of ornamentals.

8/ The cost of professional treatment would range from roughly $20.00 to $55.00 per treatment per yard (Memo 1980).

9/ Data available to the Agency indicate that neither chlorpyrifos nor endosulfan poses unreasonable adverse effects.

Because the risks and benefits associated with lindane use by commercial growers of ornamentals differ from those associated with homeowner use, the Agency has necessarily considered these two applications separately. Regarding commercial applications, the Agency has evaluated the cancer, fetotoxic, and acute toxic risks posed to applicators and has determined that under current use patterns, risks decidedly outweigh benefits. Continued, unrestricted registration has therefore been found unjustifiable. At the opposite end of the regulatory spectrum, cancellation (Option 3) would eliminate all lindane-related risks to the professional applicators involved. In view of the economic impacts (estimated at 20.6 million) expected to fall to commercial growers of ornamentals as a result of a lindane cancellation, however, and in view of the substantial reductions in risk which can be achieved by measures short of cancellation (Table IV-3), the Agency has concluded that Option 3 does not represent an appropriate risk/benefit determination in this instance. Option 2 is therefore recommended. The Agency hereby proposes that registrations of lindane products for use on commercial ornamentals be continued with the amended terms and conditions specified.

Regarding home applications, the Agency has evaluated the multiple risks posed to homeowner/applicators and has again determined that under current use patterns, benefits are clearly outweighed by risks and that Option 1 (continued, unrestricted registration) is therefore unjustifiable. Although if rigorously implemented, the provisions of Option 2 (continued registration with amended terms and conditions) would measurably reduce risks to homeowner/applicators, Option 2 would not reduce risks to a level which would ensure no adverse effects to the large number of persons involved. It is questionable, moreover, whether the protective clothing requirements of this option are practicable in connection with homeowners. In view of the risks which would continue to be posed to homeowner/applicators even when the risk-reduction provisions of Option 2 are taken into account, and in view of the largely aesthetic benefits involved, the Agency has determined that Option 2 fails to reduce risks to a level which is outweighed by benefits. Option 3 (cancellation) is therefore recommended. The Agency hereby proposes that registrations of lindane products intended for home ornamental use be cancelled.[10]

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[10] The Agency's risk/benefit determination concerning homeowner use of lindane on ornamentals was based on the application of lindane as a spray (typical formulation: 0.5 percent w/w lindane solution). The Agency is aware of a 2-percent paste formulation that is also registered for use on ornamentals. However, the Agency has no data pertaining to usage, applicator exposure, or benefits upon which to evaluate this product. Any additional information on this formulation submitted to the Agency will be taken into account in the final decision to be issued in Position Document 4.

5. Curcurbits

If registrations of lindane products for use on cucurbits were continued without restrictions (Option 1), an estimated 950 applicators would continue to be exposed to lindane via treatments with row crop boom sprayers applying a 0.06 w/w (lindane weight to water) spray. For these applicators, estimated cancer risk would remain at 4.1 X 10^{-6} and margins of safety would remain approximately 2500 (fetotoxicity) and 1250 (acute toxicity). Under Option 1, the benefits associated with lindane use on cucurbits would remain unaffected. The economic benefits associated with this use are estimated at 2.4 million dollars for Florida, South Carolina, and Georgia.[11]

If registrations of lindane products for use on cucurbits were continued with amended terms and conditions (Option 2), the following provisions would apply. All pesticide products containing lindane would be required to display the label warnings specified in Subsection IV. C.1.a. Lindane products would be classified for restricted use, and applicator certification would be required. Applicators would be required to wear protective clothing (long-sleeved work shirts and long pants). (Refer to Table IV-1.)

Implementation of these risk-reduction measures would reduce cancer risks from 4.1 X 10^{-6} to 4.0 X 10^{-7} and increase estimated margins of safety from 2500 to 25,000 (fetotoxicity) and from 1250 to 12,500 (acute effects). (Refer to Table IV-3.) The provisions of this option are expected to entail no significant impact on economic benefits.

If registration of lindane products for use on cucurbits were cancelled (Option 3), all risks associated with lindane would be eliminated. For the reasons discussed in Chapter III, cancellation of lindane would not result in significantly decreased yields. Furthermore, the minor impacts projected for increased treatment costs of alternatives, $176,000, may be high insofar as it assumes that the growers in certain areas will switch to methomyl which is by far the most expensive alternative.

The Agency has evaluated the cancer, fetotoxic, and acute toxic risks posed to applicators in conjunction with lindane use on cucurbits, and has determined that continued unrestricted registration (Option 1) is unjustifiable. Even if the risk reduction measures of Option 2 were adopted, the risks would still outweigh the benefits. Accordingly, the Agency has selected Option 3 - Cancellation.

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[11] Data concerning use on cucurbits is available only for Florida, South Carolina, and Georgia. These limitations do not allow for a measurement of the entire economic benefits.

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6. Christmas Trees

If registrations of lindane products for use on Christmas trees were continued without restriction (Option 1), an estimated 10,000 applicators (private Christmas tree growers) would continue to be exposed to lindane via foliar, stump, and trunk treatments.[12/] Cancer risks to these applicators would remain at an estimated 3.7×10^{-5} to 6.8×10^{-4} margins of safety would remain at a range of 2-37 (acute toxicity) and 4-75 (fetotoxicity). Under Option 1, the economic benefits (unquantified) associated with lindane use on Christmas trees would likewise continue unaffected.

If registrations of lindane for use on Christmas trees were continued with amended terms and conditions (Option 2), the following provisions would apply. All pesticide products containing lindane would be classified for restricted use, and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindane products. Applicators would be required to wear protective clothing and impermeable (neoprene) aprons, boots, and elbow-length gloves. (Refer to Table IV-1.) Via these risk-reduction measures, cancer risks could be reduced from an estimated $3.7 \times 10^{-5} - 6.8 \times 10^{-4}$ to $2.0 \times 10^{-5} - 1.7 \times 10^{-4}$, and margins of safety increased from 2-37 to 8-70 (acute toxicity) from 4-75 to 16-139 (fetotoxicity). (Refer to Table IV-3.) The provisions of Option 2 are expected to have a minimal impact on economic benefits.

If registrations of lindane products for use on Christmas trees were cancelled (Option 3), all lindane-related risks to applicators would be eliminated. Given a lack of data on annual usage, the economic impacts which would result from cancellation of this use were unquantifiable. Based on a qualitative analysis, however, the Agency projects that these impacts will be minor, although it is possible that certain individual growers might experience major impacts. Oxydemeton-methyl, which is approximately 1.2 to 2 times the cost per acre of lindane, is available to control one of the target pests, white pine weevils. Chemical control can also be supplemented by non-chemical cultural practices what should provide control over the insect population.

Having evaluated the cancer, fetotoxic, and acute toxic risks posed to applicators in conjunction with lindane use on Christmas trees, the Agency has determined that continued, unrestricted registration (Option 1) is unjustifiable. Option 2, which would continue registrations with amended terms and conditions, would be acceptable in this instance

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[12/] Data on the amount of lindane used annually by the Christmas tree industry were unavailable.

only if the reduced risks thereby achieved were decidedly outweighed by benefits. Given the unquantifiable benefits associated with this use together with the availability of chemical and non-chemical alternatives, and given the risks which would remain even if specified risk-reduction measures were implemented, the Agency's determination is that Option 2 is unacceptable and that cancellation (Option 3) is warranted. The Agency therefore recommends that Option 3 be implemented, and cancellation of registrations of lindane products for use on Christmas trees is hereby proposed.

7. Pecans

If registrations of lindane products for use on pecans were continued without restriction (Option 1), an estimated 1200 applicators would continue to be exposed to lindane via high-exposure spray treatments. Cancer risks to these applicators would remain at an estimated 3.1×10^{-4}, and margins of safety would remain very low: approximately 4 (acute toxicity) and 7 (fetotoxicity). Under Option 1, the economic benefits, estimated at $1.4 million, associated with lindane use on pecans would likewise continue unaffected.

If registrations of lindane for use on pecans were continued with amended terms and conditions (Option 2), the following provisions would apply. All pesticide products containing lindane would be classified for restricted use, and applicator certification would be required. The warnings to users, and to women, and to parents specified in subsection IV.C.1.a would be required to appear on the labels of all lindane products. Applicators would be required 1) to wear protective clothing (long-sleeved shirts, long pants, and wide-brimmed hats) and elbow-length impermeable (neoprene) gloves, or 2) to employ a roof-type shelter on machinery being used. (Refer to Table IV-1.) Via these risk-reduction measures, cancer risks to applicators could be reduced from 3.1×10^{-4} to 7.5×10^{-5}, and margins of safety increased from 4 to 15 (acute toxicity) and from 7 to 31 (fetotoxicity). (Refer to Table IV-3.) The provisions of Option 2 are expected to have a very minor impact on economic benefits.

If registrations of lindane products for use on pecans were cancelled (Option 3), all lindane-related risks to applicators as well as dietary cancer risk to the general public as a result of this use of the pesticide would be eliminated. The economic impacts resulting from the cancellation of the use would be negligible. Endosulfan is currently registered for pecans in Mississippi under FIFRA 24(c) and has federally approved registrations for many other crops. The Agency projects that endosulfan can be registered and used as a substitute in most areas where lindane is currently used.[13]

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[13] Data available to the Agency indicate that none of these alternatives pose unreasonable adverse effects.

Having evaluated the cancer, acute toxic, and fetotoxic risks posed to applicators the Agency has determined that these risks are unacceptably high and that continued, unrestricted registration (Option 1) is unjustifiable. Option 2, which would continue registration with amended terms and conditions, would be acceptable in this instance only if the reduced risks thereby achieved were decidedly outweighed by benefits. Given the minor economic benefits, associated with this use, and given the substantial exposure and risk which would remain even if specified risk-reduction measures were rigorously implemented, the Agency's determination is that Option 2 is unacceptable and that cancellation (Option 3) is warranted. The Agency therefore recommends that Option 3 be implemented, and cancellation of registration of lindane products for use on pecans is hereby proposed.

8. Forestry

If registrations of lindane products for use in forestry were continued without restriction (Option 1), an estimated 1000 applicators would continue to be exposed to lindane via spray treatments. Cancer risks to these applicators would remain at an estimated 1.9×10^{-3} and margins of safety would remain approximately 36 (fetotoxicity) and 18 (acute toxicity). Under Option 1, the economic benefits (unquantifiable) associated with lindane use in forestry would likewise continue unaffected.

If registrations of lindane for use in forestry were continued with amended terms and conditions (Option 2), the following terms and conditions would apply. All pesticide products containing lindane would be classified for restricted use, and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindane products. Applicators would be required to wear protective clothing and elbow-length impermeable (neoprene) gloves. (Refer to Table IV-1.) These are the same protective clothing requirements set by the U.S. Forest Service.[14/] Via these risk-reduction measures, cancer risks could be reduced from an estimated 1.9×10^{-3} to 5.5×10^{-4}, and margins of safety increased from 36 to 42 (fetotoxicity) and 18 to 21 (acute toxicity). (Refer to Table IV-3.) The provisions of Option 2 are expected to have a minimal impact on economic benefits.

If registrations of lindane for use in forestry were cancelled (Option 3), all lindane-related risks to applicators would be eliminated. Given a lack of data on annual usage, the economic impacts

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[14/] U.S. Department of Agriculture Forest Service, Southeast Area, "Strategy for the Control of Southern Pine Beetles in the Southeastern United States."

which would result from cancellation of this use were unquantifiable. However, the Agency projects that impacts would be borne by Southern forestry, primarily by private land owners. No impact could be determined for seed orchards and naval stores-producing trees. Registered alternative chemicals include endosulfan and dicrotophos. Recent test results indicate that chlorpyrifos is likely to be more effective than lindane for use in forestry. Cultural practices can also be employed to supplement these chemical alternatives.

Having evaluated the cancer, fetotoxic, and acute toxic risks posed to applicators in conjunction with lindane use in forestry, the Agency has determined that continued, unrestricted registration (Option 1) is unjustifiable. Option 2, which would continue registrations with amended terms and conditions, would be acceptable in this instance only if the reduced risks thereby achieved were decidedly outweighed by benefits. Given the unquantifiable benefits associated with this use together with the availability of alternatives, and given the substantial risks which would remain even if specified risk-reduction measures were implemented, the Agency's determination is that Option 2 is unacceptable and that cancellation (Option 3) is warranted. The Agency therefore recommends that Option 3 be implemented and proposes that registrations of lindane products for use in forestry be cancelled. The Agency makes this recommendation for all forestry uses other than those associated with broadscale blow downs of trees. In such a case, aerial application of lindane would result in lower application risks and benefit would be high. The Agency solicits comments on this and will provide a specific position in PD 4.

9. Livestock

If registrations of lindane products for use on livestock were continued without restrictions (Option 1), an estimated 250,000 applicators would continue to be exposed to lindane via dip and spray treatments. Estimated cancer risks to these applicators would remain 5.0×10^{-6} and margins of safety would remain 416 (fetotoxicity) and 208 (acute toxicity) with no change in the risks associated with dietary exposure. Under this option, the benefits associated with lindane use on livestock, estimated at $1,083,400, would likewise remain unaffected.

If registrations of lindane products for use on livestock were continued with amended terms and conditions (Option 2), the following provisions would apply. Lindane products would be classified for restricted use, and applicator certification would be required. All products would be required to display the label warnings to users, to women, and to parents specified in Subsection IV.C.1.a. Applicators would be required to wear protective clothing and impermeable (neoprene) aprons, boots, and elbow-length gloves. (Refer to Table IV-1.) Implementation of these risk reduction measures could reduce the estimated cancer risks from 5.0×10^{-6} to 1.3×10^{-6} and increase margins of safety from 416 to 1786 (fetotoxicity) and from 208 to 893 (acute toxicity). (Refer to Table IV-3.) These provisions are expected to have a negligible impact on economic benefits.

If registrations of pesticide products containing lindane for use on livestock were cancelled (Option 3), all lindane-related risks to applicators would be eliminated. Alternative chemicals would have to be substituted for lindane, resulting in a total economic impact estimated at $1,083,400.00. This represents a minor economic impact, entailing no effect on production yield or quality. However, alternatives are not as effective as lindane for control of mites, and a cancellation would leave users without any adequate means of controlling mites on livestock. A recent publication by the National Academy of Science (Langford, 1980) documents the recent spread of scabies among cattle in crowded commercial feedlots and recommends the use of lindane because a single application is effective in controlling mites. Alternatives, including coumaphos and phosmet, are less effective, require multiple applications, and are believed to lead to genetically induced resistance. The only other alternative for mite control is toxaphene, which has been presumed to pose unreasonable adverse effects and is currently under RPAR review.

Having evaluated the cancer, fetotoxic, and acute toxic risks posed to applicators as well as the dietary cancer risk posed to the general public in conjunction with lindane use on livestock, the Agency has determined that continued, unrestricted registration (Option 1) is unjustifiable. Cancellation (Option 3) would eliminate all exposure and risk associated with this use of lindane. However, Option 3 would be warranted only if measures short of cancellation would not suffice to reduce risks to a level which is outweighed by benefits. Given the benefits associated with lindane use against mites which infest livestock, and given the decreased risks associated with the implementation of the specified risk reduction measures, the Agency's determination is that cancellation (Option 3) is unwarranted. The Agency therefore recommends that Option 2 be implemented and that registrations of lindane products for use on livestock be continued with specified amended terms and conditions.

10. Structures

If registrations of lindane products for use in structures were continued without restriction (Option 1), an estimated 40,000 inhabitants (10,000-12,000 houses) and 500-1000 applicators would continue to be exposed to lindane. Cancer risks to these inhabitants and applicators would remain an estimated 4.6×10^{-4} and 4.4×10^{-3} to 8.8×10^{-3} respectively. Margins of safety for inhabitants would remain approximately 3 (acute toxicity) and 416 (fetotoxicity), while those for applicators would remain approximately 3 (acute toxicity) and 5 (fetotoxicity). These calculations apply only to adults. Margins of safety for acute effects in children are likely to be considerably lower. Under Option 1, the economic benefits (unquantified) associated with lindane use on structures would likewise continue unaffected.

If registrations of lindane for use on structures were continued with amended terms and conditions (Option 2), the following provisions would apply. All pesticide products containing lindane would be classified for restricted use and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV. C.1.a would be required to appear on the labels of all lindane products. Applicators would be required to wear protective clothing, elbow-length impermeable (neoprene) gloves and a respirator. (Refer to Table IV-1.) Via these risk reduction measures, cancer risks to applicators couldbe reduced from an estimated 4.4 x 10^{-3} - 8.8 x 10^{-3} to 1.2 x 10^{-3} - 2.5 x 10^{-3}, and margins of safety increased from 3 to 18 (acute toxicity) and from 5 to 37 (fetotoxicity). Risks to residents and their children would remain unchanged. The provisions of Option 2 are expected to have a minimal impact on economic benefits.

If registrations of lindane products for use on structures were cancelled (Option 3), all lindane-related risks to applicators and to residents would be eliminated. The economic impact of cancelling the structural use of lindane is likely to be slight because infestation can be prevented or retarded by finishing wood surfaces, where feasible, and because, in the event of infestation, PCP is available as an effective and economically competitive alternative.[15] The conclusion that cancellation of the powder post beetle use of lindane will cause minimal economic impact is supported by the fact that powder post beetle infestations spread slowly, and that not all infestations require treatment to prevent economic damage.

Having evaluated the cancer, fetotoxic, and acute toxic, and fetotoxic risks posed to applicators and to residents, especially children, in conjunction with lindane use on structures, the Agency has determined that continued, unrestricted registration (Option 1) is unjustifiable. Option 2, which would continue registrations with amended terms and conditions, would be acceptable in this instance only if the reduced risks thereby achieved were decidedly outweighed by benefits. Given the unquantifiable benefits associated with this use, and given the substantial risks which would remain even if specified risk-reduction measures were implemented, the Agency's determination is that Option 2 is unacceptable and that cancellation (Option 3) is warranted. The Agency therefore recommends that Option 3 be implemented, and cancellation of registrations of lindane products for use on structures is hereby proposed.

11. Pineapples

If registrations of lindane products for use in Hawaiian pineapple fields were continued without restriction (Option 1), an estimated 1,600 workers would continue to be exposed to lindane primarily via inhalation. However, anticipated hourly exposure (5 x 10^{-7}) is so low that risk calculations were statistically insignificant. Cancer risk is estimated at 10^{-12}, and margins of safety at 4.5 x 10^{7} (acute effects) and 2.3 x 10^{7} (fetotoxicity). Under Option 1, the benefits associated with lindane use in Hawaiian pineapple fields would likewise continue unaffected.

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[15] PCP, the state-recommended alternative to lindane, is currently under RPAR review, but does not appear to pose hazards that are worse than lindane.

If registrations of lindane for use on Hawaiian pineapple fields were continued with amended terms and conditions (Option 2), the following provisions would apply. All pesticide products containing lindanewould be classified for restricted use, and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindaneproducts. Although no measurable reductions in risk can be attributed to these provisions, the Agency maintains that restricted use classification and requirements for applicator certification and label warnings are prudentprecautionary measures in any instance involving potential exposure, howeversmall, to lindane. The provisions of Option 2 are expected to have a negligible impact on economic benefits.

If registrations of lindane for use in Hawaiian pineapple fields were cancelled (Option 3), all exposure to applicators would be eliminated. The Hawaiian Pineapple Growers Association has estimated that if lindane were unavailable for use on pineapples, the Hawaiian pineapple industry would have to absorb an economic loss of $1,108,367 (1977 dollars) over each 4-year production cycle. Cancellation of this use would mean that growers would have no method of symphylid control in cases of late infestations or adverse soil conditions. At present, there are no non-chemical methods of controlling symphylids. Certain soil fumigants which primarily control nematodes help to control symphylids, but these have no residual action and offer no protection against late infestations.[16] Moreover, soil fumigants vaporize off the fields in very moist or improperly prepared soil.

Because the cancer, fetotoxic, and acute toxic risks associated with lindane use on pineapple fields are so low as to be statistically insignificant, and because no acceptable alternatives are available which can replace lindane in its role in dual soil treatments, the Agency has determined that benefits outweigh risks even though quantifiable benefits ($1,018,367 [1977 dollars] over each 4-year production cycle) are considered minor. Cancellation (Option 3) is therefore inappropriate. Given the special sensitivity of children to the toxic effects of lindane, however, and given the susceptibility of unborn children to the fetotoxic effects of the pesticide, continued registration (Option 1) seems imprudent even though exposure and risk are very low. However, since applicators already are required to use protective clothing when using fumigants, additional requirements are unwarranted because of the extremely low carcinogenic risk. Therefore, the Agency recommends Option 2 continued registration with the general labeling precautions specified for lindane.

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[16] Dibromochloropropane (DBCP), ethylene dibromide (EDB), Telone, and DD (a mixture of 1,3 dichloropropane, 1,2 dichloropropane, and related C_3 compounds). Chloropicrin is also registered as a dual-purpose soil fumigant but is not reported used.

12. Pet Uses

a. Dog Washes

Lindane dog washes are currently available for use by both veterinarians and private pet owners. If registrations were continued without restriction (Option 1), an estimated 15,000,000 non-veterinarian applicators and an estimated 130,000 veterinarian applicators would continue to be exposed to lindane in connection with this use. Cancer risks to these applicators would remain at approximately 2.4×10^{-7}. (Post-application cancer risk is estimated at 7×10^{-8}.) Margins of safety would remain roughly 2.5×10^{5} (fetotoxicity) and 1.3×10^{5} (acute effects). (Post-application margins of safety are estimated at 1.4×10^{5} [fetotoxicity] and 0.7×10^{5} [acute effects].) However, these calculations apply only to adults. Margins of safety for acute effects in children are likely to be considerably lower. Under Option 1, the benefits (unquantifiable but assessed in qualitative terms as minor) associated with this use would continue unaffected.

If registrations were continued with amended terms and conditions (Option 2), the following provisions would apply. The warnings to users, to women, to parents specified in Subsection IV.C.1.a would be required to appear on the labels of lindane dog washes. Lindane dog washes would be classified for restricted use, the products would be designated for veterinarian application only, and veterinarians would be required to obtain applicator certification. In addition, veterinarian applicators would be required to wear protective clothing and impermeable aprons and elbow-length gloves. (Refer to Table IV-1.) Cancer risks to veterinarian applicators would thereby be reduced for an estimated 2.4×10^{-7} to 4.8×10^{-8}, and margins of safety for fetotoxicity and acute effects would be increased to 1.2×10^{6} and 6.2×10^{5} respectively (Table IV-3). Because pet owners would no longer be allowed to apply lindane dog washes, hazard to this population would be limited to post-application exposure.

If registrations were cancelled (Option 3), exposure and risk to both pet owners and veterinarians would be eliminated. In economic terms, the impact (unquantifiable) of this cancellation is expected to be minor. To cancel lindane dog washes, however, would be to remove from the market the pesticide reportedly most effective against scabies (mange)-causing mites. A single lindane application is recommended as effective against mites, whereas available alternatives require repeated applications and apparently foster genetically-induced resistance (Langford, 1980).

Having evaluated the cancer, fetotoxic, and acute toxic risks posed both to veterinarians and to pet owners, especially children, in connection with lindane dog washes, the Agency has determined that continued, unrestricted registration (Option 1) is unjustifiable. Cancellation (Option 3) would eliminate all exposure and risk in question.

In the absence of any equally effective alternative to lindane for use against scabies-causing mites, however, the Agency has concluded that Option 3 is likewise unacceptable. Option 2 is therefore recommended. The Agency proposes that registrations of lindane dog washes be continued with the specific amended terms and conditions of registration designated above.

b. Flea Collars, Dog Dusts, and Dog Shampoos

If registrations of lindane flea collars, dog dusts, and dog shampoos were continued without restriction (Option 1), an undetermined number of pet owners, including children, would continue to be exposed to lindane in connection with these primarily non-veterinarian uses.[17/] Cancer risks would remain at an estimated 2×10^{-4} (flea collars), 1.5×10^{-5} for applicators and 1.9×10^{-5} post-application (dog dusts), and 3.6×10^{-5} for applicators and 2×10^{-6} post-application (dog shampoos).

Margins of safety for fetotoxicity would remain roughly 3×10^{6} (flea collars), 83,000 (dog dusts), and 16,666 (dog shampoos). Margins of safety for acute effects would remain approximately 1.4×10^{6} (flea collars), 41,500 (dog dusts), and 8,333 (dog shampoos). Post-application MOS for dog dusts and dog shampoos would remain at 9260 (fetotoxicity) and 4630 (acute effects) and 3840 (fetotoxicity) and 1920 (acute effects), respectively. However, these calculations apply only to adults. Margins of safety for acute effects in children are likely to be considerably lower. Under Option 1, the benefits (unquantifiable but projected as minor) associated with these pet uses would likewise continue unaffected.

If registrations were continued with amended terms and conditions (Option 2), the warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindane flea collars, dog dusts, and dog shampoos. Although no measurable reduction in risk can be attributed to warning labels, the Agency considers warning statements to be a reasonable precautionary measure in any instance involving exposure to lindane. Label warning requirements are not expected to affect economic benefits.

If registrations of these pet uses were cancelled (Option 3), exposure and risk to pet owners would be eliminated. Given the general availability of effective alternatives, the impact of these cancellations is expected to be very minor, though no quantitative assessment was possible. Presently 15 chemical alternatives are registered, including carbaryl, coumaphos, pyrethrins, resmethrin, and ronnel.

[17/] In the concentrations necessary for pest control, lindane is toxic to cats, but not to dogs. Only Ohio currently recommends lindane for use against fleas on cats.

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The Agency has evaluated the cancer, fetotoxic, and acute toxic risks posed to users and especially to children in connection with lindane flea collars, dog dusts, and dog shampoos and determined that continued, unrestricted registration (Option 1) is unjustifiable. Given 1) the impracticality of any provision short of cancellation which could bring about measurable reductions in exposure and risk, 2) the likelihood that children are exposed to lindane via these pet uses, and 3) the minimal benefits involved, the Agency's determination is that Option 2 (continued registration with amended terms and conditions) is likewise unacceptable. Cancellation (Option 3) is therefore proposed. The Agency recommends that registrations of lindane flea collars, dog dusts, and dog shampoos be cancelled.

13. Household Uses

a. Shelf Paper
b. Floor Wax
c. General Purpose Household Spray
d. Smoke Fumigation Devices

If registrations of lindane shelf paper, floor wax, general purpose household spray, and smoke fumigation devices were continued without restriction (Option 1), a large number of users and their children would continue to be exposed to lindane in connection with these household uses.[18] Cancer risks would remain at approximately 3.9×10^{-5} (shelf paper), 6.7×10^{-4} (floor wax), 6.0×10^{-11} (household spray), and 1.1×10^{-3} (smoke fumigation devices). Margins of safety for fetotoxicity would remain roughly 6,000 (shelf paper), 1,250 (floor wax), 3.8×10^{7} (household spray), and 700 (smoke fumigation devices). Margins of safety for acute effects would remain roughly 3,000 (shelf paper), 625 (floor wax), 1.9×10^{7} (household spray), and 350 (smoke fumigation devices). However, these calculations apply only to adults. Margins of safety for acute effects in children are likely to be considerably lower. Under Option 1, the benefits (unquantifiable but projected as very minor) associated with lindane household uses would likewise continue unaffected.

If registrations of lindane household uses were continued with amended terms and conditions (Option 2), the warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of all lindane products intended for household use. Although no measurable reduction in risk can be attributed to label warnings, the Agency considers precautionary statements to be prudent in any instance involving exposure to lindane. Label warning requirements are not expected to affect economic benefits.

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[18] The estimated number of persons exposed annually to lindane shelf paper is 11,000,000. The number of persons exposed to floor wax is estimated at 100,000,000. The number of persons exposed annually to lindane smoke fumigation devices and household sprays could not be determined.

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If registrations of lindane shelf paper, floor wax, general purpose household spray, and smoke fumigation were cancelled (Option 3), all lindane-related risks to users would be eliminated. The economic impact of these cancellations is expected to be minor, though data limitations have precluded quantitative assessment. Numerous alternatives to lindane for these household purposes are currently available, including diazinon, malathion, naphthalene, paradichlorobenzene, methoxychlor, and dichlorvos.

Having evaluated the cancer, fetotoxic, and acute toxic risks posed to users and especially to children in connection with lindane household uses, the Agency has determined that continued, unrestricted registration (Option 1) is unjustifiable. In view of 1) the impracticality of any provision short of cancellation which could measurably reduce exposure and risk, 2) the inevitable exposure of children in connection with these household uses, and 3) the minimal benefits involved, the Agency's determination is that Option 2 (continued registration with amended terms and conditions) is likewise unacceptable. Cancellation (Option 3) is therefore recommended. The Agency proposes that registrations of lindane shelf paper, floor wax, general purpose household spray, and smoke fumigation devices be cancelled.

14. Minor Uses

a. Minor Uses Specifically Under Review

1) Industrial Use Moth Spray
2) Uninhabited Building Insect Spray
3) Empty Storage Bin Fog Spray

If registrations of the above named minor uses were continued without registration (Option 1), an undetermined number of applicators would continue to be exposed to lindane. Post-application exposure is also involved wherever industrial moth spray is used. Cancer risks would remain at 1.3×10^{-6} for applicators and 1.1×10^{-5} for post-application exposure (moth spray), 1.9×10^{-6} (uninhabited building insect spray), and 5.5×10^{-5} (empty storage bin fog spray). Margins of safety for fetotoxicity would remain at 8×10^{4} and 800 (moth spray: applicator and post-application exposure, respectively), 135 (uninhabited building insect spray), and 39 (empty storage bin fog spray). Margins of safety for acute effects would remain at 5×10^{6} and 400 (moth spray: applicator and post-application exposure, respectively), 68 (uninhabited building insect spray), and 20 (empty storage bin fog spray). Under Option 1, the benefits (unquantifiable but projected as minor) associated with these uses would likewise continue unaffected.

If registrations were continued with amended terms and conditions (Option 2), the following provisions would apply. The pesticide products in question would be classified for restricted use, and applicator certification would be required. The warnings to users, to women, and to parents specified in Subsection IV.C.1.a would be required to appear on the labels of these products. The provisions of Option 2 are expected to have a negligible impact on economic benefits.

If registrations were cancelled (Option 3), all exposure and risk associated with these minor uses would be eliminated. No data concerning the economic benefits of these uses are available to the Agency. In the absence of such information, given the lengthy public notice and the attempts by the EPA/USDA/State assessment team to obtain data the Agency must proceed on the assumption that the economic impacts of these cancellations would be minimal.

In view of the cancer, fetotoxic, and acute toxic risks posed to applicators in conjunction with those minor uses which are specifically under review, and in view of the minimal benefits involved, the Agency has determined that neither Option 1 (continued, unrestricted registration) nor Option 2 (continued registration with amended terms and conditions) is justifiable. Option 3 (cancellation) is therefore recommended. The Agency proposes that registrations of the minor uses of lindane be cancelled.

b. Other Minor Uses

In addition to those minor uses of lindane specifically under review, the numerous other minor uses of lindane are recommended for cancellation. These include use of lindane on lettuce, mushrooms, tomatoes, apples, apricots, asparagus, broccoli, Brussels sprouts, cabbage, cauliflower, celery, cherries, collards, eggplants, grapes, guavas, kale, kohlrabi, mangoes, mustard greens, nectarines, okra, onions, peaches, pears, peppers, plums, spinach, quinces, strawberries and Swiss chard. Together these crop uses likely account for a sizable proportion of the dietary intake and risk (Table II-6).

B. Summary of Proposed Regulatory Decision

1. Hardwood Logs and Lumber

Option 3. Cancel registrations to take effect after two years.

During this 2-year phase-out/interim period, the following amended terms and conditions of registration will apply. Lindane products will be classified for restricted use, and applicator certification will be required. Specified warnings to users, to women, and to parents must appear on the labels of all lindane products.[19] Applicators will be required to wear impermeable protective clothing (neoprene aprons, neoprene boots, and elbow-length neoprene gloves).

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[19] Warnings are quoted in Subsection IV.C.1.a.

2. Seed Treatment

Option 3. Cancel registrations.

3. Avocados

Option 3. Cancel registrations.

4. Ornamentals

a. Commercial Use

Option 2. Continue registrations with the following amended terms and conditions of registration. Lindane products for commercial use will be classified for restricted use, and applicator certification will be required. Specified warnings to users, to women, and to parents must appear on the labels of all lindane products. Commercial applicators will be required to wear protective clothing (long-sleeved work shirts and long pants), elbow-length impermeable (neoprene) gloves, and a respirator.

b. Homeowner Use

Option 3. Cancel registrations.

5. Cucurbits

Option 3. Cancel registrations.

6. Christmas Trees

Option 3. Cancel registrations.

7. Pecans

Option 3. Cancel registrations.

8. Forestry

Option 3. Cancel registrations.

9. Livestock

Option 2. Continue registrations with the following amended terms and conditions of registration. Lindane products will be classified for restricted use, and applicator certification will be required. Specified warnings to users, to women, and to parents must appear on the label of all lindane products. Applicators will be required to wear protective clothing (long-sleeved work shirts and long pants), elbow-length impermeable (neoprene) gloves, neoprene aprons, and neoprene boots.

10. Structures

Option 3. Cancel registrations.

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11. Pineapples

Option 2. Continue registrations with the following amendment to the terms and conditions of registration. Specified warnings to users, to women, and to parents must appear on the labels of all lindane products.

12. Pet Uses

a. Dog Washes

Option 2. Continue registrations with the following amended terms and conditions. Lindane products will be classified for restricted use and limited to veterinarian applications only; applicator certification will be required. Specified warnings to users, to women, and to parents must appear on the labels of all lindane products. Veterinarian applicators will be required to wear protective clothing (long-sleeved work shirts and long pants), elbow-length impermeable (neoprene) gloves and neoprene aprons.

b. Flea Collars, Dog Dusts, and Dog Shampoos

Option 3. Cancel registrations.

13. Household Uses

Option 3. Cancel registrations.

14. Minor Uses

Option 3. Cancel registrations.

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* Copies of specific references will be provided on request. There will be a charge to cover duplication costs for such requests. A copy of the Position Document and all references are available for public inspection in the office of the Special Pesticide Review Division (TS-791), Crystal Mall II, Room 718, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460. References with the notation "Cited in Position Document 1" are on file with that document.

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4A	Burroughs Wellcome Company
4B	Burroughs Wellcome Company
4C	Burroughs Wellcome Company
6C	Reed and Carnrick Pharmaceuticals
7A	Millen Industries
13	U.S. Dept. of Agricu
18A	Athena Corporation
19	Continental Chemiste Corporation
19A	[461 F.2d 331 (7th Cir Docket #71-1828, 1972)]
26	Terminix International
37	Franklin Laboratories
38	Chevron Chemical Co.
41	Paper Products, Inc.
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42	Hooker Chemicals and Plastics Corporation
42C	Hooker Chemicals and Plastics Corporation
43	The Environmental Defense Fund
49	U.S. Dept. of Agriculture

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